

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: STANFORD UNIVERSITY  
ARRILLAGA ALUMNI CENTER  
MC CAW HALL  
326 GALVEZ STREET  
STANFORD, CALIFORNIA

DATE: FRIDAY, FEBRUARY 10, 2006  
8:30 A.M.

REPORTER: BETH C. DRAIN, CSR  
CSR. NO. 7152

BRS FILE NO.: 74245

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1           STANFORD, CALIFORNIA; FRIDAY, FEBRUARY 10, 2006

2                           09:52 A.M.

3

4                   CHAIRMAN KLEIN:  IF WE COULD ALL BE SEATED,  
5   PLEASE.  ALL RIGHT.  IF WE COULD BEGIN THE MEETING, WE  
6   HAVE A HEAVY AGENDA TODAY.  I'D LIKE TO ASK THAT THE  
7   ICOC MEMBERS PLEASE TAKE THEIR CHAIRS.  THANK YOU VERY  
8   MUCH.

9                   I'D LIKE TO WELCOME ALL OF YOU HERE TODAY TO  
10   STANFORD.  AND TO MY RIGHT OUR DISTINGUISHED BOARD  
11   MEMBER DR. PHIL PIZZO, CHAMPIONS OF CHRONIC DISEASE  
12   RESEARCH AND MEDICAL RESEARCH GENERALLY, IS OUR HOST.  
13   THANK YOU, DR. PIZZO.  ALSO THANKING HIS STAFF FOR  
14   THEIR ASSISTANCE, KRISTIN GOLDTHORPE, MIRA ENGEL, AND  
15   NYELL VARGAS, AS WELL AS KRISTIN GILLAM FROM THE ALUMNI  
16   CENTER.  IT'S AN HONOR TO BE HERE.

17                  MELISSA KING, COULD YOU LEAD US IN THE FLAG  
18   SALUTE, PLEASE.

19                           (THE PLEDGE OF ALLEGIANCE.)

20                  CHAIRMAN KLEIN:  WE HAD A TREMENDOUS  
21   SPOTLIGHT THIS MORNING, AND I AM GOING TO COVER JUST AN  
22   ITEM ON THE SPOTLIGHT, AND THEN GO THROUGH THE ROLL  
23   CALL.  FIRST OF ALL, I'D LIKE TO THANK DR. BLUESTONE,  
24   DR. GERMAN FROM UC SAN FRANCISCO, SON KIM MAY BE HERE  
25   IN THE AUDIENCE FROM STANFORD, ONE OF THE GREAT AND

1 BRILLIANT STARS AT STANFORD DEALING WITH DIABETES. I  
2 WOULD ALSO LIKE TO THANK COLE CONROY, BERNIE REVAK, AND  
3 DANA LEWIS FOR THEIR PERSONAL STORIES, AND CERTAINLY  
4 THE ALLIANCE FOR STEM CELL RESEARCH FOR THE ASSISTANCE.  
5 MELISSA KING, PLEASE CALL THE ROLL.  
6 MS. KING: PAUL JENNINGS FOR DAVID BALTIMORE.  
7 DR. JENNINGS: HERE.  
8 MS. KING: ROBERT BIRGENEAU.  
9 DR. BIRGENEAU: HERE.  
10 MS. KING: DAVID MEYER FOR KEITH BLACK.  
11 DR. MEYER: HERE.  
12 MS. KING: SUSAN BRYANT.  
13 DR. BRYANT: HERE.  
14 MS. KING: MARCY FEIT. MICHAEL FRIEDMAN.  
15 DR. FRIEDMAN: HERE.  
16 MS. KING: MICHAEL GOLDBERG.  
17 MR. GOLDBERG: HERE.  
18 MS. KING: FRANCIS MARKLAND FOR BRIAN  
19 HENDERSON.  
20 DR. MARKLAND: HERE.  
21 MS. KING: ED HOLMES.  
22 DR. HOLMES: HERE.  
23 MS. KING: DAVID KESSLER. BOB KLEIN.  
24 CHAIRMAN KLEIN: HERE.  
25 MS. KING: SHERRY LANSING.

1 MS. LANSING: HERE.  
2 MS. KING: GERALD LEVEY. TED LOVE.  
3 DR. LOVE: HERE.  
4 MS. KING: RICHARD MURPHY. TINA NOVA.  
5 DR. NOVA: HERE.  
6 MS. KING: ED PENHOET.  
7 DR. PENHOET: HERE.  
8 MS. KING: PHIL PIZZO.  
9 DR. PIZZO: HERE.  
10 MS. KING: CLAIRE POMEROY.  
11 DR. POMEROY: HERE.  
12 MS. KING: FRANCISCO PRIETO.  
13 DR. PRIETO: HERE.  
14 MS. KING: JOHN REED.  
15 DR. REED: HERE.  
16 MS. KING: JOAN SAMUELSON.  
17 MS. SAMUELSON: HERE.  
18 MS. KING: DAVID SERRANO-SEWELL.  
19 MR. SERRANO-SEWELL: HERE.  
20 MS. KING: JEFF SHEEHY.  
21 MR. SHEEHY: HERE.  
22 MS. KING: JONATHAN SHESTACK.  
23 MR. SHESTACK: HERE.  
24 MS. KING: OSWALD STEWARD. LEON THAL.  
25 DR. THAL: HERE.

1 MS. KING: JANET WRIGHT.

2 DR. WRIGHT: HERE.

3 CHAIRMAN KLEIN: THANK YOU, MELISSA. I'D  
4 LIKE TO MOVE TO AGENDA ITEM 5, CONSENT ITEMS, APPROVAL  
5 OF THE MINUTES FROM DECEMBER 6, 2005, MEETINGS. IS  
6 THERE A MOTION FROM THE BOARD TO ACCEPT THOSE MINUTES?

7 MR. GOLDBERG: SO MOVED.

8 CHAIRMAN KLEIN: MOTION HAS BEEN MADE. IS  
9 THERE A SECOND?

10 DR. LOVE: SECOND.

11 CHAIRMAN KLEIN: ALL IN FAVOR. OPPOSED?  
12 MOTION PASSES.

13 I'D LIKE TO ASK -- I WAS TOLD THERE WAS NO  
14 PUBLIC COMMENT, BUT OBVIOUSLY THAT'S DIFFICULT TO TELL.  
15 IS THERE ANY PUBLIC COMMENT THERE ON THAT ITEM? I  
16 INTENDED TO ACTUALLY ASK FOR IT AHEAD OF TIME. I DON'T  
17 SEE ANY PUBLIC COMMENT ON THAT ITEM.

18 GOING TO ITEM NO. 6, THE CHAIRMAN'S REPORT.  
19 I WOULD LIKE TO BEGIN BY SAYING THAT ONE OF THE GREAT  
20 FIRSTS OF PROPOSITION 71 IS THAT FOR THE FIRST TIME IN  
21 THE HISTORY OF THE STATE OF CALIFORNIA AN INDEPENDENT  
22 CITIZENS COMMITTEE HAS BEEN CREATED BY AN INITIATIVE TO  
23 OVERSEE THE AGENCY'S FINANCIAL OPERATIONS AND  
24 PERFORMANCE. THIS HAS NOT EVER BEEN TRUE BEFORE IN THE  
25 HISTORY OF THE STATE. IT'S CALLED THE CITIZENS

1 FINANCIAL ACCOUNTABILITY OVERSIGHT COMMITTEE.

2 THIS COMMITTEE HAS APPOINTMENTS BY THE  
3 PRESIDENT PRO TEM OF THE SENATE, THE SPEAKER OF THE  
4 ASSEMBLY, BY THE TREASURER AND CONTROLLER, I MAKE AN  
5 APPOINTMENT AS CHAIRMAN OF THIS BOARD, AND THE  
6 CONTROLLER SITS AS THE CHAIRMAN OF THAT COMMITTEE.

7 IN THE INTERIM BETWEEN THE LAST BOARD  
8 MEETING, I HAVE MADE THE APPOINTMENT FOR THIS BOARD  
9 BEING MYRTLE POTTER, A PERSON OF GREAT DISTINCTION WITH  
10 A CAREER THAT ENDED AT THE VERY TOP LEVELS OF  
11 GENENTECH. SHE IS AN INDIVIDUAL WHO, BECAUSE OF A VERY  
12 CRITICAL INJURY AND COMPLICATIONS, LEFT THE BIOTECH  
13 SECTOR AND IS NOW DEVELOPING AFFORDABLE HOUSING,  
14 SOMETHING I DEEPLY APPLAUD, BUT IS SOMEONE WHO HAS  
15 NEVERTHELESS HAD A LIFE DEDICATED TO THE DEVELOPMENT OF  
16 THERAPIES AND THE FIGHT AGAINST CHRONIC DISEASE,  
17 SOMEONE WHO WE HOPE WILL MAKE A GREAT CONTRIBUTION ON  
18 THAT OVERSIGHT COMMITTEE.

19 THE OVERSIGHT COMMITTEE IS THE CENTERPIECE OF  
20 WHAT THE CONTROLLER IS BUILDING AS THE GOLD STANDARD  
21 FOR FINANCIAL OVERSIGHT PERFORMANCE IN CALIFORNIA.  
22 YESTERDAY THE CONTROLLER PROCEEDED ON THE AGENDA TO  
23 ADVANCE THAT GOLD STANDARD OF FINANCIAL OVERSIGHT. WE  
24 NEED TO REMEMBER THAT HIS FINANCIAL OVERSIGHT BEGAN  
25 WITH THE VERY FIRST DAYS OF THE CREATION OF THIS

1 INITIATIVE. INDEED HE ISSUED A LETTER ON DECEMBER 17TH  
2 OF 2004 TO SET A PATHWAY TO FINANCIAL ACCOUNTING AND  
3 OVERSIGHT EXCELLENCE, WHICH WE HAVE BEEN WORKING WITH  
4 HIM ON FROM THAT EARLY BEGINNING STAGE OF THE  
5 INSTITUTE.

6 IN FACT, ONE OF THE FIRST PRIMARY STAFF  
7 MEMBERS TO THIS AGENCY WAS ON LOAN ORIGINALLY FROM THE  
8 CONTROLLER'S OFFICE. WALTER BARNES, A VETERAN OF 40  
9 YEARS OF STATE SERVICE, CAME TO GIVE US DIRECT ON-SITE  
10 GUIDANCE IN FINANCIAL OVERSIGHT AND COMPLIANCE WITH  
11 STRICT AUDIT AND FINANCIAL REVIEW PRACTICES OF THE  
12 CONTROLLER'S OFFICE, AND OUR FOUNDATION FOR  
13 ACCOUNTABILITY HAS BEEN BUILT WITH THAT KNOWLEDGE AND  
14 GUIDANCE.

15 THE DECEMBER 17TH LETTER COVERED THE START-UP  
16 OF THE FINANCIAL PROCESS FOR DOCUMENTATION OF ALL  
17 PAYMENTS, DISCUSSION OF AN ANNUAL REVIEW AND AUDIT,  
18 REPORTING TO TAXPAYERS, TRANSPARENCY AND DISCLOSURE  
19 PROVISIONS, AND OTHER PROVISIONS THAT IN DETAIL BUILT A  
20 SOUND SYSTEM. WE ARE GOING TO HEAR LATER TODAY THAT  
21 WE'RE PROCEEDING THROUGH OUR FIRST ANNUAL AUDIT AND  
22 EXPECT TO WORK VERY CLOSELY WITH THE STATE CONTROLLER'S  
23 OFFICE AS HE DOES, IN FACT, BUILD THE GOLD STANDARD FOR  
24 FINANCIAL AND PERFORMANCE OVERSIGHT FOR THE STATE OF  
25 CALIFORNIA, OF WHICH WE ARE PROUD TO BE A PART AND



1 EMBRACE HIS EFFORTS.

2 SECOND ITEM TO COVER TODAY IS, AS REPORTED IN  
3 THE RECENT MEDIA, THE BRIDGE FINANCING EFFORT IS MOVING  
4 WELL. ACHIEVING THE \$50 MILLION BENCHMARK CHALLENGE  
5 ANNOUNCED IN THE NOVEMBER MEETING FOR THE FIRST TIME  
6 WILL REQUIRE AN ADDITIONAL NOTICED MEETING OF THE  
7 FINANCE COMMITTEE OF THE STATE TO FINALIZE ALL THE  
8 TERMS THAT HAVE BEEN NEGOTIATED WITH THE PARTICIPANTS  
9 WITH THE HELP OF THE STATE TREASURER'S OFFICE. STATE  
10 TREASURER'S OFFICE WILL SET UP THE TIMELINE FOR CLOSING  
11 AFTER THAT FINANCE COMMITTEE IS HELD, WHICH MAY TAKE  
12 SOME FIVE TO SIX WEEKS FROM THAT TIME TO FUNDING.

13 WE EXPECT THAT OF THE \$50 MILLION, IT WILL BE  
14 CLOSED IN INCREMENTS, OBVIOUSLY WITH THE FIRST  
15 INCREMENT BEING DEDICATED TO THE FELLOWSHIP PROGRAM,  
16 WHICH WE NEED IMMEDIATELY.

17 I'D LIKE TO PARTICULARLY EXPRESS MY  
18 APPRECIATION TO THOSE BOARD MEMBERS WHO HAVE BEEN VERY  
19 ACTIVE IN THE LAST INCREMENT OF TIME SINCE THE FINAL  
20 BOARD MEETING: SHERRY LANSING, DR. REED, DR. HOLMES,  
21 DR. FRIEDMAN, DR. LEVEY, DR. MURPHY, DR. NOVA, AND  
22 ALTERNATE BOARD MEMBER DR. DAVID MEYER. IT TAKES A  
23 GREAT EFFORT OF MANY OF US TOGETHER WORKING TOGETHER TO  
24 ACCOMPLISH OUR GOALS, AND IT'S VERY IMPORTANT TO  
25 REALIZE THAT THERE'S A LOT OF THANKS TO BE SPREAD

1     AROUND IN THIS EFFORT.

2                 FINALLY, THE STATE TREASURER'S OFFICE, WITH  
3     THE HELP OF THEIR CONSULTANTS, MONTAGUE AND DE ROSE,  
4     ARE PREPARING A QUESTION-AND-ANSWER TUTORIAL THAT WILL  
5     BE PUT UP ON THE WEBSITE ON BOND AND BOND PARTICIPATION  
6     NOTE ISSUES, INCLUDING COMPARING TAXABLE AND TAX-EXEMPT  
7     BONDS. DOUG MONTAGUE AND JIM BEAMIS UNDER THE  
8     DIRECTION AND SUPPORT OF JUAN HERNANDEZ, THE DEPUTY  
9     STATE TREASURER, ARE GOING TO BE WORKING ON THIS, AND  
10    IT SHOULD BE POSTED NEXT WEEK ACCORDING TO THEIR  
11    SCHEDULE.

12                I'D LIKE TO NOW TURN THIS OVER TO OUR  
13    DISTINGUISHED PRESIDENT, DR. ZACH HALL.

14                DR. HALL: THANKS, BOB. LET ME JUST SAY GOOD  
15    MORNING TO THE MEMBERS OF THE ICOC MEETING AND THE  
16    PUBLIC. AND I WANT TO BEGIN THIS MORNING, BECAUSE WE  
17    ARE IN THE BAY AREA, WE HAVE A NUMBER OF STAFF HERE.

18                CHAIRMAN KLEIN: WHILE DR. HALL IS MASTERING  
19    THE TECHNOLOGY HERE, AS ALWAYS, WE SHOULD THANK OUR  
20    BRILLIANT STAFF FOR THE DEDICATION WITH WHICH THEY  
21    HANDLE ALL OF THESE MEETINGS.

22                DR. HALL: IT DOESN'T SEEM TO BE A  
23    FUNDAMENTAL CHARACTER DEFECT, BUT SOMETHING ELSE.

24                I WANT TO BEGIN JUST BY INTRODUCING A NUMBER  
25    OF OUR STAFF WHO HAVEN'T BEEN ABLE TO MAKE THE MEETINGS

1     BEFORE.  YOU'VE HEARD ABOUT MOST OF THEM, BUT I WOULD  
2     JUST LIKE FOR YOU TO GET A CHANCE TO SEE THEM AND  
3     INTRODUCE THEM IN PERSON.  THEY ARE ALEXANDRA CAMPE,  
4     OUR CHIEF HUMAN RESOURCES OFFICER, WHO'S HERE, WHO CAME  
5     TO US SOME TIME AGO FROM UCSF; TRICIA CHIVIRA, OUR  
6     GRANTS TECHNICAL ASSISTANT, WHO HAS BEEN PROVIDING  
7     GREAT SUPPORT FOR ARLENE AND THE SCIENCE TEAM; AND DAN  
8     BEDFORD, OUR INTERIM LEGAL COUNSEL, WHO I MENTIONED  
9     BEFORE IS WORKING WITH US ON A PRO BONO BASIS, AND  
10    WE'VE BEEN DELIGHTED TO HAVE HIM.

11               I WOULD ALSO LIKE TO INTRODUCE AN IMPORTANT  
12    NEW ADDITION TO OUR TEAM, AND THAT IS DALE CARLSON, WHO  
13    HAS JOINED US FOR A SHORT PERIOD OF TIME OR FOR AN  
14    INDEFINITE PERIOD OF TIME.  ONE OF THOSE TWO IS TRUE.  
15    HE IS AN INTERIM SENIOR COMMUNICATIONS OFFICER, AND HE  
16    HAS BEEN EXTREMELY HELPFUL TO US ALREADY.  DALE, WHERE  
17    ARE YOU?  WILL YOU STAND, PLEASE?  DALE HAS BEEN WITH  
18    THE PACIFIC STOCK EXCHANGE FOR 14 YEARS WHERE HE WAS  
19    THE VICE PRESIDENT FOR CORPORATE AFFAIRS THERE AND  
20    HANDLED PRESS AND MEDIA RELATIONS, INVESTOR RELATIONS,  
21    GOVERNMENT AND PUBLIC AFFAIRS, AND HE'S ALSO BEEN  
22    ACTIVE IN PUBLIC SERVICE WITH THE PUBLIC LIBRARY,  
23    TREASURE ISLAND AUTHORITY, AND OTHERS.  HE'S BEEN A  
24    TREMENDOUS ADDITION TO OUR TEAM, AND IS GOING TO BE  
25    WORKING WITH US PART TIME OVER THE NEXT SOME MONTHS.

1                   NOW, I WANT TO BEGIN BY MAKING A FEW REMARKS.  
2   THIS IS THE FIRST MEETING IN THIS YEAR, AND I'D LIKE TO  
3   JUST LOOK BACK BRIEFLY ON WHERE WE'VE COME DURING THE  
4   PAST YEAR AND LOOK FORWARD TO THE COMING YEAR, IF I  
5   MAY.

6                   I THINK ALL OF US WOULD AGREE THAT WE'VE HAD  
7   A SOMEWHAT TUMULTUOUS FIRST YEAR. WE'VE HAD A NUMBER  
8   OF -- EXCITING YEAR. WE'VE HAD A NUMBER OF CHALLENGES  
9   BOTH LOCALLY AND WORLDWIDE. AND I WANT TO SAY THAT I  
10  THINK THE ICOC AND THE CIRM STAFF HAVE RESPONDED TO  
11  THESE CHALLENGES SUPERBLY. WE'VE HAD THE USUAL BUMPS  
12  OF ANY ORGANIZATION AND WE'VE HAD SOME IN ADDITION; AND  
13  I THINK IN SPITE OF THESE DIFFICULTIES, IF WE LOOK  
14  BACK, WE CAN BE PROUD OF WHAT WE'VE ACCOMPLISHED DURING  
15  THIS LAST YEAR.

16                  THE ICOC HAS BEEN ORGANIZED AND HAS BECOME A  
17  FUNCTIONING UNIT, BRINGING TOGETHER PEOPLE FROM THE  
18  WORLD OF ACADEMIA AND RESEARCH, FROM PATIENT ADVOCACY,  
19  AND FROM THE PRIVATE SECTOR. THE ICOC HAS ESTABLISHED  
20  OUR WORKING GROUPS. ALL THREE OF THESE WORKING GROUPS  
21  HAVE MET, AND TWO OF THEM, THE GRANTS GROUP AND  
22  STANDARDS GROUP, HAVE ALREADY DONE MAJOR SUBSTANTIVE  
23  WORK. WE'VE ADDED CRITICAL NEW SCIENTIFIC AND  
24  ADMINISTRATIVE PERSONNEL. WE HAVE CHOSEN A SITE AND  
25  DESIGNED NEW OFFICES. WE'VE ISSUED OUR FIRST RFA,

1     REVIEWED THE APPLICATIONS, AND APPROVED OUR FIRST  
2     GRANTS, ALL WORKING IN A NEW, MORE TRANSPARENT FORMAT  
3     THAT HAS POSED CHALLENGES FOR BALANCING OUR VARIOUS  
4     PRIORITIES.

5             AND FINALLY, WE HAVE HELD OUR FIRST  
6     SCIENTIFIC CONFERENCE, COMPLETE WITH A WRITE-UP OF THE  
7     CONFERENCE WHICH IS ALMOST COMPLETE, AND I HAVE HERE A  
8     DRAFT OF THAT. IT WILL BE READY FOR YOU SHORTLY. WE  
9     ARE IN THE VERY FINAL STAGES OF MAKING THE LAST  
10    CORRECTIONS. WE HAD HOPED TO HAVE IT READY FOR THIS  
11    MEETING, BUT DIDN'T QUITE MAKE IT. SO I WANT YOU TO  
12    KNOW IT IS CLOSE AND WE'LL HAVE IT IN YOUR HANDS SOON.

13            MOST IMPORTANTLY, WE HAVE CARRIED A MAJOR  
14    BODY OF ADMINISTRATIVE AND POLICY WORK THAT WILL REACH  
15    CULMINATION IN THIS MEETING TODAY WITH THE PRESENTATION  
16    OF THREE DOCUMENTS TO THE ICOC THAT REPRESENT THE  
17    FOUNDATION OF OUR INSTITUTE POLICIES FOR RESEARCH.  
18    THEY ARE THE INTELLECTUAL PROPERTY POLICY, THE MEDICAL  
19    AND ETHICAL STANDARDS, AND OUR GRANTS ADMINISTRATION  
20    POLICY. AND I THINK YOU WILL FIND THAT WITH RESPECT TO  
21    EACH OF THESE AREAS, CIRM, THE ICOC, AND CALIFORNIA HAS  
22    GONE ABOVE AND BEYOND THE NATIONAL STANDARDS IN EACH OF  
23    THESE AREAS. AND WE, I BELIEVE, ARE TRULY SETTING A  
24    NEW STANDARD THAT THE REST OF THE COUNTRY AND, INDEED,  
25    THE WORLD CAN FOLLOW.

1                   I'M VERY PROUD OF WHAT IS REPRESENTED TODAY,  
2   AND I SIMPLY WANT TO TAKE THIS OPPORTUNITY TO THANK THE  
3   MEMBERS OF THE ICOC, MEMBERS OF THE PUBLIC, AND OUR  
4   PUBLIC REPRESENTATIVES IN BOTH THE LEGISLATURE AND THE  
5   GOVERNOR'S OFFICE FOR THEIR STRONG SUPPORT AND FOR  
6   THEIR ACTIVE AND ONGOING CONTRIBUTIONS TO OUR WORK,  
7   MUCH OF WHICH WILL BE REPRESENTED IN WHAT YOU WILL HEAR  
8   LATER TODAY.

9                   NOW, I'D LIKE TO JUST SAY THAT OUR EFFORTS  
10   HAVE NOT GONE UNRECOGNIZED ON THE INTERNATIONAL SCENE.  
11   I WANT TO TELL YOU BRIEFLY ABOUT TWO RECENT INVITATIONS  
12   THAT HIGHLIGHT OUR STANDING.   FIRST, CIRM HAS RECEIVED  
13   AN INVITATION TO JOIN THE INTERNATIONAL STEM CELL  
14   FORUM.   THE INTERNATIONAL FORUM, COMPOSED LARGELY OF  
15   NATIONAL RESEARCH ORGANIZATIONS FROM DIFFERENT  
16   COUNTRIES, WAS FORMED TO PROMOTE INTERNATIONAL  
17   COOPERATION AND COLLABORATION IN STEM CELL RESEARCH  
18   THROUGH PROMOTING COMPATIBLE ETHICAL AND SCIENTIFIC  
19   STANDARDS AMONG DIFFERENT COUNTRIES.

20                  AT THE RECENT MEETING, THE INTERNATIONAL  
21   FORUM INVITED REPRESENTATIVES OF ITALY, CHINA, AND  
22   CALIFORNIA TO JOIN THEIR MEMBERSHIP.   SO WE ARE VERY  
23   PLEASED WITH THIS AND DELIGHTED BECAUSE THIS IS THE KEY  
24   INTERNATIONAL ORGANIZATION IN STEM CELL RESEARCH TODAY  
25   AT AN ADMINISTRATIVE LEVEL.   THERE IS A SCIENTIFIC

1 ORGANIZATION, BUT THIS IS THE KEY ONE FOR SETTING  
2 STANDARDS FOR WORKING OUT ADMINISTRATIVE PROBLEMS AND  
3 ACTUALLY ENGAGING IN PROJECTS WHICH WILL MAKE MORE  
4 TRANSPARENT THE WORK THAT GOES ON IN EACH OF THE  
5 DIFFERENT COUNTRIES.

6 SECONDLY, THE HEAD OF THE MRC, THE MEDICAL  
7 RESEARCH COUNCIL, OF THE UNITED KINGDOM, WHICH IS  
8 ROUGHLY EQUIVALENT TO OUR NIH, HAS WRITTEN TO US TO  
9 INVITE US TO HOLD A JOINT, ORDINARILY WE CALL IT A  
10 BI-NATIONAL MEETING, SCIENTIFIC MEETING, IN WHICH 16 UK  
11 SCIENTISTS AND 16 CALIFORNIA SCIENTISTS WILL MEET IN  
12 THE UK TO FOCUS ON A SPECIFIC TOPIC ISSUE IN STEM CELL  
13 RESEARCH. THEY HOPE THIS WILL BE THE FIRST OF A SERIES  
14 OF RECIPROCAL MEETINGS. THERE WILL BE OPPORTUNITY AT  
15 THE MEETING FOR CALIFORNIA SCIENTISTS TO VISIT  
16 INDIVIDUAL LABORATORIES, AND, AGAIN, THE OBJECT IS TO  
17 PROMOTE COLLABORATION.

18 I WANT TO SAY THAT WE ARE VERY PLEASED WITH  
19 THIS BECAUSE GREAT BRITAIN IS ONE OF THE COUNTRIES NOW  
20 THAT I THINK IS LEADING THE WORLD BOTH SCIENTIFICALLY  
21 AND IN ADMINISTRATIVE AND OTHER MATTERS IN STEM CELL  
22 RESEARCH. WE HAVE A GREAT DEAL TO LEARN FROM THEM.  
23 AND I ACTUALLY WANT TO GIVE CREDIT TO STEVEN LYNN AND  
24 THE BRITISH CONSULATE IN SAN FRANCISCO, WHO HAVE BEEN  
25 VERY, VERY HELPFUL IN FACILITATING CONTACTS AND BEEN

1     VERY GENEROUS IN PROVIDING US ACCESS TO PEOPLE THERE  
2     WITH THE EXPERIENCE THAT WE NEED.   SO THIS IS A  
3     WONDERFUL OPPORTUNITY.

4                             (APPLAUSE.)

5                     DR. HALL:   AT ANY RATE I THINK IT DOES NEED  
6     POINTING OUT, BUT IN BOTH OF THESE INSTANCES IN WHICH  
7     THE IMPORTANCE OF OUR CONTRIBUTION IS RECOGNIZED ON THE  
8     WORLD STAGE, CALIFORNIA HAS BECOME A SORT OF SURROGATE  
9     FOR THE UNITED STATES EFFORT WITH RESPECT TO EMBRYONIC  
10    STEM CELL RESEARCH.   OKAY.

11                    AFTER THIS YEAR OF ACHIEVEMENT, WHAT DOES THE  
12    NEW YEAR BRING?   AND WE HAVE BOTH NEW CHALLENGES AND  
13    NEW OPPORTUNITIES.   I THINK ALL OF US KNOW THAT THE  
14    LITIGATION THAT HAS BEEN BROUGHT AGAINST THE INSTITUTE  
15    AND THE ICOC AND THE FINANCIAL LIMITATIONS THAT HAVE  
16    RESULTED FROM THAT LITIGATION HAVE CAUSED US TO ALTER  
17    OUR ORIGINAL COURSE AND IN SOME CASES TO RESHAPE OUR  
18    GOALS AND STRATEGIES FOR THE COMING YEAR.   THIS IS  
19    IMPORTANT BECAUSE, ALTHOUGH WE'VE ALWAYS BEEN CONFIDENT  
20    OF ULTIMATE VICTORY IN THE COURTS, UNTIL RECENTLY IT'S  
21    BEEN VERY DIFFICULT TO ESTIMATE THE OVERALL TIME COURSE  
22    OF THE LEGAL APPEALS PROCESS.

23                    AS YOU ALL KNOW, I PRESUME, WE HAVE A TRIAL  
24    DATE OF FEBRUARY 27TH, AND THIS ALLOWS US TO ESTIMATE  
25    THAT IF WE COUNT THE TRIAL AND SUBSEQUENT APPEALS,



1     THESE ARE LIKELY TO LAST FOR ROUGHLY 15 MONTHS FROM  
2     NOW.  IN OTHER WORDS, AND HERE'S THE POINT I WANT TO  
3     MAKE, IT WILL BE THE SPRING OF 2007 APPROXIMATELY  
4     BEFORE WE WILL BE TO ABLE TO PURSUE STEM CELL RESEARCH  
5     ON THE SCALE THAT THE VOTERS WHO SUPPORTED PROPOSITION  
6     71 ASKED FOR AND EXPECT.

7                 SO WHAT ARE OUR PLANS DURING THIS INTERIM  
8     PERIOD?  WE HAVE TWO MAJOR GOALS.  THE FIRST IS TO  
9     SUSTAIN OUR SCIENTIFIC VITALITY AND MOMENTUM AND TO  
10    EXTEND IT.  SECOND, WE WANT TO USE THE OPPORTUNITY THAT  
11    OUR ENFORCED DELAY GIVES US TO LAY A FOUNDATION THAT  
12    WILL ALLOW US TO IMPLEMENT OUR PROGRAM AT FULL SPEED IN  
13    THE SPRING OF 2007.

14                MY ORIGINAL MODEL FOR HOW WE WOULD GROW WAS  
15    AS FOLLOWS.  WE ALL WANTED TO GET THE RESEARCH GOING AS  
16    SOON AS POSSIBLE.  AND SO MY SENSE WAS THAT WE WOULD DO  
17    BEST TO BEGIN WITH TRAINING GRANTS, WHICH ARE  
18    ADMINISTRATIVELY FAIRLY SIMPLE.  WE HAD RELATIVELY FEW  
19    APPLICATIONS JUST BY THEIR NATURE.  AND THEN FROM THAT  
20    EASY AND SIMPLE BEGINNING, WE COULD INCREMENTALLY BUILD  
21    OUR EXPERTISE AND CAPABILITY; I.E., WE WOULD SLOWLY  
22    SCALE UP TO THE TREMENDOUS TASK THAT WE HAVE AHEAD OF  
23    US.

24                I THINK WITH THE DELAY THAT WE HAVE IN THIS  
25    YEAR, WE MUST TAKE A DIFFERENT TACK.  WE HAVE TO USE

1     THIS YEAR TO PREPARE OURSELVES SO THAT WHEN THE PUBLIC  
2     MONEY BECOMES AVAILABLE, WE CAN HIT THE GROUND RUNNING.  
3     IN FACT, I THINK BECAUSE OF THE LOST SCIENTIFIC TIME,  
4     WE HAVE AN OBLIGATION TO THE VOTERS AND TO THE PATIENTS  
5     AND THEIR FAMILIES TO BE ABSOLUTELY READY TO START AT  
6     FULL TILT WHEN PUBLIC MONEY BECOMES AVAILABLE. I'LL  
7     HAVE MORE TO SAY ABOUT SOME OF THE SPECIFICS OF THAT  
8     LATER ON IN THE MEETING.

9             LET ME SPEAK TO EACH OF THESE TWO GOALS IN  
10    TURN, IF I MAY. FIRST, WE MUST MAINTAIN A STRONG  
11    SCIENTIFIC PRESENCE BECAUSE THIS IS WHAT WE'RE ALL  
12    ABOUT. IT IS OUR CENTRAL MISSION. WE CANNOT AFFORD TO  
13    LOSE THE MOMENTUM OF HOPE AND SCIENTIFIC EXPECTATION  
14    THAT PROPOSITION 71 HAS BROUGHT US.

15            FIRST AND FOREMOST, WE WANT TO BE ABLE TO  
16    AWARD THE TRAINING GRANTS THAT WE HAVE APPROVED SO THAT  
17    INSTITUTIONS CAN BEGIN SERIOUS TRAINING OF BASIC  
18    SCIENTISTS AND CLINICIANS IN STEM CELL RESEARCH. THIS  
19    WILL START THE PIPELINE OF YOUNG, NEW INVESTIGATORS WHO  
20    WILL BE SO VITAL TO THE FUTURE OF STEM CELL RESEARCH.

21            SECONDLY, WE WANT TO BE ABLE TO FUND AT LEAST  
22    ONE ROUND OF INNOVATION OR SEED GRANTS. AND AS YOU  
23    KNOW, OUR CHAIRMAN, BOB KLEIN, AND HIS TEAM HAVE BEEN  
24    BUSY RAISING THE BRIDGE FUNDING THROUGH THE BAN'S THAT  
25    WILL FUND THESE TWO RESEARCH INITIATIVES. AS YOU

1 HEARD, WE ARE VERY OPTIMISTIC ABOUT THIS AND VERY  
2 HOPEFUL OF SOON COMPLETING THE GOAL OF \$50 MILLION THAT  
3 WILL BE AVAILABLE TO FUND THESE INITIATIVES.

4 NOW, SECONDLY, WE THEN NEED A SCIENTIFIC  
5 PLAN. IF WE ARE GOING TO BEGIN OUR FULL-SCALE  
6 ACTIVITIES, WE NEED A SCIENTIFIC PLAN THAT WILL GUIDE  
7 US IN HOW WE BEGIN AND SPEND OUR MONEY. WE DISCUSSED  
8 THIS LAST TIME AT SOME LENGTH, AND I WILL PRESENT TO  
9 YOU LATER IN THE MEETING A PLAN FOR A PLAN. CLAIRE  
10 POMEROY, I THINK THAT WAS THE PHRASE, A PLAN FOR A PLAN  
11 ABOUT HOW DO WE GO ABOUT DEVELOPING THIS SCIENTIFIC  
12 STRATEGIC PLAN; BUT I THINK YOU UNDERSTAND IF WE ARE TO  
13 BEGIN AT FULL TILT NEXT SPRING, WE WILL NEED TO HAVE  
14 THAT IN PLACE SO THAT WE KNOW WHERE WE'RE GOING AND  
15 WHAT WE'RE TRYING TO DO AND HAVE SOME SENSE OF  
16 DIRECTION AND PURPOSE RIGHT FROM THE VERY BEGINNING.

17 SECONDLY, WE HAVE SPOKEN BEFORE. WE HAVE  
18 SEVERAL SCIENTIFIC PROJECTS THAT CIRM ITSELF WOULD LIKE  
19 TO CARRY OUT. ONE IS THE MEETING ON ASSESSMENT OF  
20 MEDICAL RISK FOR EGG DONATION, WHICH YOU'VE PREVIOUSLY  
21 HEARD ABOUT. AND LET ME SIMPLY SAY HERE THAT THE  
22 SOCIETY FOR GYNECOLOGIC INVESTIGATION, WHICH IS THE  
23 LEADING INTERNATIONAL SOCIETY FOR GYNECOLOGIC RESEARCH,  
24 HAS AGREED TO CO-SPONSOR THIS MEETING WITH US, AND THE  
25 NATIONAL ACADEMIES AND INSTITUTE OF MEDICINE HAVE

1     AGREED TO PUT THE MEETING ON FOR US.   AND I WILL COME  
2     BACK TO THAT BRIEFLY LATER.

3                 NEXT, WE WOULD LIKE TO PROVIDE FUNDS FOR  
4     CALIFORNIA INVESTIGATORS WHO PARTICIPATE IN THE  
5     UK-CALIFORNIA SO-CALLED BI-NATIONAL OR STATE-NATIONAL  
6     MEETING THAT I MENTIONED EARLIER.   THE TOPIC OF THE  
7     MEETING IS STEM CELL SELF-RENEWAL AND DIFFERENTIATION,  
8     AND THEY HAVE ASKED US TO PAY FOR THE INVESTIGATORS WHO  
9     WOULD PARTICIPATE IN THAT MEETING.   AND SO THAT IS ONE  
10    OF OUR PROJECTS.

11                NEXT, WE REMAIN INTERESTED IN STARTING AN  
12    ONLINE OPEN-ACCESS JOURNAL FOR STEM CELL RESEARCH THAT  
13    WILL ALLOW RESEARCHERS AND LAY PEOPLE ANYWHERE IN THE  
14    WORLD TO ACCESS THE LATEST STEM CELL RESEARCH WITH  
15    INTERPRETIVE MATERIAL.   AND AGAIN, I'LL COMMENT ON THIS  
16    BRIEFLY LATER.

17                AND THEN FINALLY, WE WOULD LIKE TO SPONSOR A  
18    MEETING NEXT FALL FOR CALIFORNIA STEM CELL SCIENTISTS  
19    SO THAT ON THE EVE OF INITIATING OUR LARGE-SCALE  
20    PROJECT, WE CAN BRING TOGETHER THOSE IN CALIFORNIA WHO  
21    ARE WORKING ON STEM CELLS, BOTH BASIC AND CLINICAL  
22    SCIENTISTS.   WE CAN GET TO KNOW THEM.   WE CAN HAVE THEM  
23    GET TO KNOW EACH OTHER.   WE CAN ASSESS THE STATE OF  
24    STEM CELL RESEARCH IN CALIFORNIA.   AND WE SEE THIS AS A  
25    SORT OF INITIAL MEETING BEFORE THE GRANTS OF OUR

1 SCIENTIFIC CONSTITUENTS, THE PEOPLE WHO WILL BE  
2 ACTUALLY DOING THE WORK IN CALIFORNIA. WE WOULD ALSO  
3 LIKE TO INCLUDE AT THAT MEETING OUR NEW TRAINEES BEING  
4 TRAINED BY THE TRAINING GRANTS AT THE VARIOUS  
5 INSTITUTIONS. SO WE SEE THIS AS A VERY, VERY IMPORTANT  
6 SORT OF COMING TOGETHER OF THE CALIFORNIA FORCES BEFORE  
7 WE BEGIN OUR WORK AT TOP SPEED.

8 NOW, LET ME ADDRESS THE SECOND PART OF THIS,  
9 WHICH IS THE INFRASTRUCTURE. IF, IN FACT, WE'RE GOING  
10 TO HIT THE GROUND RUNNING, WE HAVE A LOT OF WORK TO DO  
11 ON THE INFRASTRUCTURE SIDE. WE WILL BE HANDLING NOT 26  
12 GRANT APPLICATIONS, BUT WE WILL BE LITERALLY HANDLING  
13 HUNDREDS OF GRANT APPLICATIONS AND DOZENS OF GRANTS,  
14 AND WE WILL NEED TO DO THIS IN A RESPONSIBLE AND  
15 EFFICIENT WAY. LET ME JUST SAY THAT THIS IS A SCALEUP  
16 OVER AN ORDER OF MAGNITUDE OF WHAT WE'VE BEEN DOING AND  
17 INVOLVES A DEGREE OF ORGANIZATION AND MANPOWER THAT WE  
18 DON'T PRESENTLY HAVE.

19 WE NEED TO ADD AND TRAIN BOTH SCIENTIFIC AND  
20 ADMINISTRATIVE PERSONNEL, AND WE NEED INVESTMENT AND  
21 DEVELOPMENT OF OUR I.T. INFRASTRUCTURE IN ORDER TO  
22 HANDLE THIS LOAD. OUR GOAL IN THAT REGARD IS TO HAVE A  
23 SINGLE, SEAMLESS SYSTEM THAT WILL ALLOW US TO HANDLE  
24 APPLICATIONS, REVIEW, AWARD, AND TRACKING OF GRANTS,  
25 ALL WEB-BASED. THERE ARE A VERY FEW COMMERCIAL SYSTEMS

1 THAT ARE AVAILABLE FOR THIS PURPOSE, AND EVEN THE BEST  
2 OF THEM MUST BE ADAPTED TO OUR NEEDS, AGAIN, REQUIRING  
3 TIME AND PERSONNEL.

4 AND FINALLY, OF COURSE, WE NEED TO COMPLETE  
5 OUR POLICIES FOR INTELLECTUAL PROPERTY, MEDICAL AND  
6 ETHICAL STANDARDS, GRANTS ADMINISTRATION, AND CONVERT  
7 THESE TO STATE REGULATIONS. SO WE HAVE A LOT OF WORK  
8 AHEAD OF US, AND WE HAVE AMBITIOUS PLANS FOR THE COMING  
9 YEAR WITH RESPECT TO SCIENTIFIC PROJECTS.

10 NOW, UNFORTUNATELY OUR CURRENT BUDGET DOES  
11 NOT INCLUDE EXPENSES FOR ANY OF THESE ITEMS. THAT IS,  
12 WE ARE OPERATING ON A VERY LEAN BUDGET. WE DON'T HAVE  
13 BUDGET APPROVAL FOR ANY OF THE SCIENTIFIC PROJECTS THAT  
14 I MENTIONED, FOR ANY OF THE SCALEUP THAT I MENTIONED IN  
15 INFRASTRUCTURE, AND ALL THAT ARE ACTIVITIES WE NEED  
16 MONEY FOR.

17 NOW, I'VE MENTIONED THAT WE HAVE A BAN'S  
18 FUND-RAISING EFFORT SPEARHEADED BY BOB KLEIN AND HIS  
19 TEAM, AND THEIR IMMEDIATE GOAL IS \$50 MILLION, AND THIS  
20 WILL PROVIDE SUPPORT FOR THE GRANTS PROGRAM. HOWEVER,  
21 IF WE TAKE OUT OF THAT AN AMOUNT OF MONEY EQUAL TO THE  
22 PROPOSITION 71 FORMULA FOR ADMINISTRATIVE EXPENSES,  
23 THIS WILL NOT BE ENOUGH TO ALLOW US TO INCREASE THE  
24 SCOPE OF OUR ACTIVITIES OR HIRE MORE PEOPLE. IT WILL  
25 SIMPLY EXTEND OUR LIFETIME AT OUR CURRENT VERY LEAN

1     SIZE.

2                   SO THE CONCLUSION OF THIS IS THAT WE  
3     OBVIOUSLY NEED MONEY TO FUND AND SUPPORT OUR SCIENTIFIC  
4     ACTIVITIES.   AND ED PENHOET AND I ARE LEADING A  
5     SEPARATE FUND-RAISING EFFORT TO RAISE GIFTS, 2 TO \$2.5  
6     MILLION IN GIFT MONEY, THAT WILL SUPPORT THE PROJECTS  
7     THAT I HAVE MENTIONED AND THAT WILL US LET HIRE TWO TO  
8     FOUR SCIENTIFIC PERSONNEL AT A MINIMUM, BOTH SCIENTIFIC  
9     PROGRAM OFFICERS AND A GRANTS MANAGEMENT OFFICER.

10                  SO AN IMPORTANT PART OF OUR EFFORT DURING THE  
11     COMING MONTHS WILL BE TO MANAGE THE VERY LEAN BUDGET  
12     THAT WE'RE NOW ON AND TO RAISE MONEY TO SUPPLEMENT THAT  
13     BUDGET FOR THE VERY NECESSARY ACTIVITIES THAT I THINK  
14     WE MUST ACCOMPLISH DURING THIS YEAR.   WE ARE QUITE  
15     OPTIMISTIC ABOUT OUR ABILITY TO DO THAT LARGELY BECAUSE  
16     WE BELIEVE THAT THE ACTIVITIES THAT WE WANT TO SUPPORT  
17     ARE COMPELLING.   IT IS THOSE ACTIVITIES THAT WILL KEEP  
18     US ALIVE AS AN AGENCY AND WILL ALLOW US TO REMAIN  
19     ACTIVE AND VISIBLE DURING THIS IMPORTANT COMING YEAR.  
20     THANK YOU VERY MUCH.

21                               (APPLAUSE.)

22                  CHAIRMAN KLEIN:   THANK YOU VERY MUCH, DR.  
23     HALL.   I WOULD LIKE TO SAY THAT WHILE DR. PENHOET IS  
24     GOING TO THE MICROPHONE FOR AGENDA ITEM 8, THAT IN LINE  
25     WITH DR. HALL'S COMMENTS ABOUT THE INTERNATIONAL

1 COLLABORATIVE FOCUS ON CALIFORNIA, DR. DYNES, BOB  
2 DYNES, PRESIDENT OF THE UC SYSTEM, RECENTLY CONVENED A  
3 MEETING BETWEEN CANADA AND CALIFORNIA TO LOOK AT FIVE  
4 AREAS OF STRATEGIC COLLABORATION, INCLUDING HIGH TECH  
5 AND BIOTECH AND HEALTH.

6 IN THE BIOTECH AND HEALTH AREA, I WAS ASKED  
7 TO ADDRESS TWO SECTIONS OF THAT MEETING. DR. SUSAN  
8 BRYANT WAS THERE AS WELL.

9 IT IS MY UNDERSTANDING THAT THEY ARE NOW  
10 PREPARING A PROPOSAL TO COME TO THE ICOC, WHICH I WILL  
11 CONVEY TO DR. HALL AND DR. PENHOET, TO SEE WHAT OUR  
12 FEASIBLE COLLABORATION MIGHT BE WITH CANADA. AGAIN,  
13 THEY ARE TALKING ABOUT THE TWO COUNTRIES, CANADA AND  
14 CALIFORNIA, COLLABORATING ON THIS ADVANCED AREA OF  
15 RESEARCH.

16 PRIOR TO INTRODUCING THIS NEXT ITEM, I'D LIKE  
17 RECOGNIZE BOARD MEMBER DR. PIZZO.

18 DR. PIZZO: I THINK WE WOULD BE REMISS AS WE  
19 LOOK BACK AND LOOK FORWARD AS A BOARD IF WE DIDN'T  
20 ACKNOWLEDGE THE WORK OF ZACH HALL, WHO ACTUALLY HAS  
21 PLAYED SUCH AN IMPORTANT LEADERSHIP ROLE. SO, ZACH,  
22 THANK YOU VERY MUCH FOR THAT.

23 (APPLAUSE.)

24 DR. PIZZO: I JUST WANT TO MAKE ONE OTHER  
25 COMMENT VERY BRIEFLY. THAT IS, IN LIGHT OF THE EVER



1 ELUCIDATING THE CLARIFICATION ABOUT CALIFORNIA AS A  
2 NATION, IT PLAYS, I THINK, A VERY IMPORTANT ROLE TODAY  
3 IN TERMS OF WHAT'S HAPPENING FOR THE FUNDING OF  
4 BIOMEDICAL RESEARCH IN THE UNITED STATES. AS WE ALL  
5 KNOW, THE NIH BUDGET HAS REACHED A FLAT LINE. THIS HAS  
6 TREMENDOUS IMPLICATIONS OBVIOUSLY FOR RESEARCH AND FOR  
7 OUR MEDICAL COMMUNITY BROADLY. AND, IN FACT, FOR THOSE  
8 REASONS, THE AVAILABILITY OF SUPPORT THROUGH CIRM WILL  
9 MAKE A TREMENDOUS DIFFERENCE GOING FORWARD, NOT ONLY  
10 FOR STEM CELL RESEARCH, BUT FOR BIOMEDICAL RESEARCH IN  
11 GENERAL, AND JUST ANOTHER REASON WHY CALIFORNIA WILL  
12 TAKE A LEADERSHIP ROLE IN THE NATION, SO WE SHOULD  
13 ACKNOWLEDGE THAT AS WELL.

14 CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR.  
15 PIZZO.

16 THE NEXT ITEM, ITEM 8, CONSIDERATION OF  
17 REPORT FROM THE IP TASK FORCE. I'D LIKE TO RECOGNIZE  
18 THAT DR. EDWARD PENHOET, A MEMBER OF OUR BOARD AND VICE  
19 CHAIR, WAS IN ONE OF HIS FORMER LIVES OF DEDICATION TO  
20 PUBLIC SERVICE THE DEAN OF THE SCHOOL OF PUBLIC HEALTH  
21 AT BERKELEY. IT'S A TREMENDOUS DISTINGUISHED AREA OF  
22 LEADERSHIP IN HEALTH POLICY, AND I HAD THE PRIVILEGE OF  
23 SPEAKING THERE AND BEING INTRODUCED BY DR. BIRGENEAU  
24 THIS LAST WEEK. BUT IT IS A TREMENDOUS ADVANTAGE FOR  
25 US TO HAVE THE STRATEGIC INSIGHT AND HISTORY OF DR.

1 PENHOET LOOKING AT HEALTH POLICY FROM AN ACADEMIC VIEW  
2 AND NOW FROM A PRIVATE VIEW AND AS A VICE CHAIRMAN OF  
3 THIS BOARD. HE WAS HEROICALLY ASSISTED BY MARY MAXON,  
4 WHO PUT IN UNTOLD HOURS IN THIS EFFORT. DR. PENHOET.

5 DR. PENHOET: THANK YOU. THE ITEM BEFORE US  
6 IS APPROVAL OF THE CIRM INTELLECTUAL PROPERTY POLICY  
7 FOR NONPROFIT ORGANIZATIONS, WHICH HAS BEEN SENT TO ALL  
8 OF YOU. WE HAVE RECEIVED -- WE HAD A NUMBER OF  
9 MEETINGS, AS WE DISCUSSED LAST TIME. WE HAVE RECEIVED  
10 INPUT ALL ALONG IN THIS PROCESS FROM A WIDE VARIETY OF  
11 CONSTITUENTS. WE HAVE RECEIVED MORE INPUT IN THE LAST  
12 FEW DAYS, AND ON THE BACK TABLE, WHEREVER THE TABLE IS  
13 WITH ALL THE DOCUMENTS, IT'S OUTSIDE, ARE COPIES OF  
14 LETTERS FROM VARIOUS INTERESTED PARTIES.

15 I'M PLEASED TO BE ABLE TO TELL YOU THERE'S NO  
16 ONE IS COMPLETELY HAPPY WITH THIS POLICY, WHICH MEANS  
17 WE HAVE PROBABLY FOUND A REASONABLE COMPROMISE  
18 SOMEWHERE THE MIDDLE OF ALL THIS. BUT IT'S A  
19 CONTROVERSIAL AREA, AND I THINK WE WORKED VERY HARD --  
20 WHEN I SAY WE, THE TASK FORCE THAT'S BEEN LED BY  
21 MYSELF, BUT INCLUDES MANY MEMBERS OF THIS COMMISSION  
22 WHO HAVE WORKED DILIGENTLY AND VERY HARD TO COME UP  
23 WITH THE PROPOSAL THAT WE HAVE HERE IN FRONT OF YOU  
24 TODAY.

25 BEFORE WE DIVE INTO THE DETAILS OF THIS, I

1 WOULD, FIRST OF ALL, JUST LIKE TO RECOGNIZE THAT WE'RE  
2 ON THE STANFORD CAMPUS. AND YOU SAW FROM MIKE GERMAN'S  
3 PRESENTATION THE TERRIFICALLY INTERESTING FULL SCIENCE  
4 AROUND THE DEVELOPMENT OF THE PANCREAS. THE FIELD WAS  
5 REALLY STARTED BY A PROFESSOR AT STANFORD, CHAIR OF THE  
6 BIOLOGY DEPARTMENT, CLIFFORD GROBSTEIN, WHO WAS THE  
7 FIRST TO SHOW THAT SOLUBLE FACTORS GROW THE  
8 DIFFERENTIATION OF THE PANCREAS. SO IN A SENSE WE'RE  
9 AT GROUND ZERO FOR THE WHOLE FIELD OF PANCREAS  
10 DIFFERENTIATION. JUST WANTED TO MAKE THAT COMMENT  
11 GIVEN THE FACT WE ARE ON THAT CAMPUS.

12 AND HAVING SAID THAT, I'D LIKE TO INTRODUCE  
13 JAMES HARRISON, WHO WILL JUST REMIND US ABOUT THE  
14 PROCESS GOING FORWARD ONCE WE APPROVE THIS POLICY  
15 TODAY, HOPEFULLY WE WILL DO THAT, WHAT THAT MEANS IN  
16 TERMS OF THE FUTURE WE HAVE IN FRONT OF US, AND HOW  
17 THESE POLICIES BECOME REGULATION.

18 MR. HARRISON: AS WE DISCUSSED PREVIOUSLY,  
19 PROPOSITION 71 AUTHORIZES YOU AS A BOARD TO ADOPT  
20 INTERIM REGULATIONS THAT ARE OUTSIDE THE SCOPE OF THE  
21 ADMINISTRATIVE PROCEDURE ACT. THIS ENABLES YOU TO  
22 ADOPT THESE GUIDELINES FOR INTELLECTUAL POLICY APPLIED  
23 TO NONPROFIT GRANT RECIPIENTS TODAY. THEY, THE  
24 REGULATIONS YOU ADOPT, WILL REMAIN IN EFFECT FOR 270  
25 DAYS DURING WHICH TIME THEY WILL GO THROUGH THE FORMAL

1 ADMINISTRATIVE PROCEDURE ACT RULEMAKING PROCESS,  
2 INCLUDING A PUBLIC HEARING AND PUBLIC COMMENT.

3 THEY WILL THEN BE ADOPTED AS FINAL  
4 REGULATIONS BY YOU AS A BOARD AT THE CLOSE OF THE  
5 PUBLIC COMMENT PERIOD AND GO TO THE OFFICE OF  
6 ADMINISTRATIVE LAW FOR REVIEW. ONCE THE OFFICE OF  
7 ADMINISTRATIVE LAW APPROVES THEM, THEY WILL BECOME  
8 FINAL REGULATIONS AND REPLACE THE INTERIM REGULATIONS  
9 YOU ADOPT TODAY.

10 DR. PENHOET: THANK YOU. PROCEDURALLY THE  
11 DOCUMENT YOU'VE ALL RECEIVED HAS THREE SECTIONS. THE  
12 FIRST SECTION IS LARGELY BACKGROUND MATERIAL, THE  
13 SECOND SECTION THE GUIDELINES FOR THE PRODUCTION OF THE  
14 EVENTUAL REGULATIONS, AND THE THIRD SECTION BEING A  
15 POLICY SECTION, WHICH IS POLICY WHICH WILL BECOME  
16 POLICY OF THE CIRM, BUT WILL NOT BE INCORPORATED INTO  
17 THE STATE REGULATIONS UNDER APA. SO WE'RE GOING TO  
18 FOCUS THE DISCUSSION THIS MORNING ON THE CENTRAL  
19 SECTION, SECTION II, BECAUSE SECTION II IS THE PART  
20 THAT WILL BECOME THE SUBJECT OF THE APA REGULATIONS AS  
21 WE GO FORWARD; AND, THEREFORE, IT'S IN MANY SENSES THE  
22 MOST IMPORTANT PART OF THIS.

23 ONE OF THE THINGS WE'VE ENJOYED AS A TASK  
24 FORCE IN THE LAST SIX MONTHS THAT WE'VE BEEN WORKING ON  
25 THIS PROJECT IS A VERY VIGOROUS DIALOGUE WITH VARIOUS

1 PARTIES INTERESTED IN THIS SUBJECT, AND WE HAVE  
2 AFFORDED THEM LOTS OF TIME DURING OUR MEETINGS TO  
3 PROFESS THEIR VIEWS AND TO HAVE REAL INPUT INTO THE  
4 PROCESS. TODAY WE UNFORTUNATELY DON'T HAVE THAT MUCH  
5 TIME. WE HAVE LOTS OF OTHER THINGS ON THE AGENDA, SO  
6 WE WILL HAVE TO LIMIT PUBLIC COMMENT TO OUR USUAL THREE  
7 MINUTES. SO THOSE OF YOU WHO WOULD LIKE TO COMMENT ON  
8 THIS, WE WILL GIVE YOU AMPLE OPPORTUNITY TO DO THAT,  
9 BUT WE HAVE TO LIMIT IT BECAUSE OF THE OVERALL  
10 CONSTRAINTS OF THE TIME WE FACE TODAY.

11 SINCE OUR LAST MEETING -- AT THE LAST MEETING  
12 WE DEVELOPED THE FIVE CORE PRINCIPLES COLLECTIVELY AS A  
13 GROUP IN THE LAST L.A. ICOC MEETING. WE PROVIDED AN  
14 INTERIM DOCUMENT, A LONG ACRONYM THERE, THE  
15 INTELLECTUAL PROPERTY POLICY FOR NONPROFIT  
16 ORGANIZATIONS, WAS PROVIDED TO THE TASK FORCE AND  
17 POSTED. THE TASK FORCE MET AGAIN AND DISCUSSED AND  
18 APPROVED REALLY A MATURATION OF THE FIVE PRINCIPLES  
19 INTO A MORE FLESHED-OUT DOCUMENT, WHICH YOU HAVE IN  
20 FRONT OF YOU TODAY. WE HAD THAT MEETING HERE AT  
21 STANFORD, AND WE HAD LOTS OF INPUT TO THAT MEETING.

22 THE IP TASK FORCE UPDATE WAS PROVIDED TO THE  
23 STANDARDS WORKING GROUP, WHICH BY PROP 71 HAS A ROLE OF  
24 REVIEWING THIS MATERIAL, AND JEFF SHEEHY PRESENTED THAT  
25 TO THAT GROUP. THE DOCUMENT WAS REVISED, SENT TO ALL

1 OF YOU, AND POSTED. AND TODAY I'M HERE TO PRESENT TO  
2 YOU THE WORK OF OUR ENTIRE GROUP.

3 SO TO REFRESH YOUR MEMORY, THESE WERE THE  
4 CORE QUESTIONS THAT GUIDED OUR IP DISCUSSIONS. WHO  
5 SHOULD OWN ANY INVENTIONS THAT ARISE FROM THE FUNDING?  
6 HOW SHALL WE AS CIRM REQUIRE THE SHARING OF DATA TOOLS,  
7 TECHNOLOGY, AND INTELLECTUAL PROPERTY? THREE, SHOULD  
8 CIRM CREATE A RESEARCH EXEMPTION FOR THE USE OF IP FOR  
9 BASIC RESEARCH PURPOSES? FOUR, WHAT LICENSING  
10 REQUIREMENTS SHOULD BE ADOPTED BY OUR CIRM GRANTEEES?  
11 AND THEN FINALLY, SHOULD CIRM RETAIN MARCH-IN RIGHTS?

12 JUST TO GIVE YOU A QUICK OVERVIEW ANSWER TO  
13 NO. 1 IS WE BELIEVE THE GRANTEEES SHOULD OWN THE  
14 INVENTIONS. NO. 2, THAT WE ARE PROPOSING TO PUSH THE  
15 ENVELOPE OF WHAT'S TRADITIONALLY BEEN DONE IN THE AREA  
16 OF SHARING OF DATA TOOLS, TECHNOLOGY, AND INTELLECTUAL  
17 PROPERTY. AN IMPORTANT MANIFESTATION OF THAT IS THAT  
18 THE ANSWER TO NO. 3 IS, YES, WE SHOULD CREATE A  
19 RESEARCH EXEMPTION FOR THE USE OF INTELLECTUAL  
20 PROPERTY. IN RECOMMENDING THIS, WE HAVE TAKEN INTO  
21 ACCOUNT THE FACT THAT SUCH AN EXEMPTION MAY HAVE A  
22 CONSEQUENCE OF DECREASING THE COMMERCIAL OPPORTUNITY  
23 FOR RESEARCH TOOLS, ETC., AND WE SHOULD TALK ABOUT THAT  
24 AS ONE OF THE ITEMS AS WE GO THROUGH THIS TODAY.

25 WE HAVE A FAIRLY EXTENSIVE SECTION IN YOUR

1 DOCUMENT ABOUT LICENSING REQUIREMENTS ON COMMERCIAL  
2 ORGANIZATIONS. THE WORK OF OUR COMMITTEE WAS REALLY TO  
3 BALANCE RETURN TO THE STATE, THE ISSUES OF SHARING OF  
4 DATA AND INFORMATION, THE WIDESPREAD USE OF OUR  
5 TECHNOLOGY, AT THE SAME TIME TRYING TO ENSURE THAT WE  
6 DON'T GO SO FAR DOWN THAT PATH, THAT WE REALLY  
7 DISCOURAGE THE COMMERCIALIZATION OF THE TECHNOLOGY  
8 BECAUSE THERE IS AN AWARENESS ON ALL OF OUR PARTS THAT  
9 DIAGNOSTICS, THERAPIES, ETC., WILL ONLY REACH PATIENTS  
10 IF THEY ARE TAKEN UP BY THE PRIVATE SECTOR. SO WE  
11 WORKED HARD TO ACHIEVE WHAT WE THINK IS AN APPROPRIATE  
12 BALANCE IN THAT REGARD.

13 AND FINALLY, WE BELIEVE THAT CIRM SHOULD  
14 RETAIN MARCH-IN RIGHTS TO PROTECT THE INTERESTS OF THE  
15 CITIZENS OF CALIFORNIA UNDER CERTAIN CIRCUMSTANCES.  
16 THOSE ARE THE QUESTIONS.

17 THIS IS WHAT WE DECIDED LAST TIME, AND I  
18 THINK ALL OF YOU HAVE THIS IN YOUR BOOK. I'VE JUST  
19 GONE THROUGH THIS VERBALLY. WE DO SUPPORT A BROAD  
20 SHARING POLICY, WE WILL CREATE A RESEARCH EXEMPTION,  
21 THAT WE WILL HAVE A RETURN TO THE STATE, AND THAT A  
22 DIRECT FINANCIAL RETURN TO THE STATE IN ADDITION TO ALL  
23 OF THE OTHER RETURNS WHICH WE'VE TALKED ABOUT WHICH ARE  
24 NOT DIRECTLY FINANCIAL, BUT OBVIOUSLY HAVE FINANCIAL  
25 IMPLICATIONS. AND FINALLY, THAT WE WILL HAVE MARCH-IN

1 RIGHTS AS PART OF THIS.

2 SO AS I SAID, THERE ARE THREE SECTIONS.

3 WE'RE GOING TO FOCUS NOW IN THIS DISCUSSION ON SECTION  
4 II BECAUSE THIS IS THE PART WHICH WILL EVENTUALLY HAVE  
5 THE FORCE OF LAW IN THE STATE OF CALIFORNIA.

6 WITHIN SECTION II, THERE ARE THREE PARTS:  
7 SECTION G, INVENTION REPORTING REQUIREMENTS; H, SHARING  
8 OF CIRM-FUNDED INTELLECTUAL PROPERTY; AND, I, MARCH-IN  
9 RIGHTS.

10 I PROPOSE ACTUALLY THAT WE ATTEMPT TO APPROVE  
11 THESE SECTIONS EACH INDIVIDUALLY BECAUSE THE WHOLE  
12 PACKAGE IS A VERY LARGE PACKAGE. SO I WOULD LIKE TO  
13 PROCEED BY ANALYZING EACH OF THESE SECTIONS ON ITS OWN.  
14 THE FIRST IS THE REPORTING REQUIREMENTS. YOU CAN READ  
15 THIS FOR YOURSELF. FIRST OF ALL, WE WANT TO PUSH FOR  
16 PROMPT DISCLOSURE OF INVENTIONS MADE IN THE PERFORMANCE  
17 OF CIRM RESEARCH. THAT'S WHAT NO. 1 SAYS. NO. 2, IN A  
18 LOT OF THIS WE TRIED TO CONFORM AS MUCH AS POSSIBLE TO  
19 THE REQUIREMENTS OF THE NATIONAL INSTITUTES OF HEALTH  
20 SO AS TO NOT UNNECESSARILY BURDEN OUR GRANTEE  
21 INSTITUTIONS WITH A DIFFERENT SET OF REPORTING  
22 REQUIREMENTS UNLESS THERE WAS SOME CLEAR REASON WHY  
23 THOSE DIFFERENT SET OF REPORTING REQUIREMENTS COME INTO  
24 PLAY IN THIS CIRCUMSTANCE. SO THE TIMING, ETC., OF  
25 WHEN THESE INVENTIONS SHOULD BE DISCLOSED AND THE WAY



1 IN WHICH THEY ARE DESCRIBED, ETC., IS INDICATED HERE IN  
2 THESE FIRST TWO SLOTS.

3 HERE, NO. 3, I WANT TO MAKE A COMMENT UPON  
4 BECAUSE WE DID RECEIVE COMMENTS ON ITEM 3. GRANTEE  
5 ORGANIZATIONS MUST NOTIFY CIRM ON AN ANNUAL BASIS  
6 REGARDING THE FILING OF PATENT APPLICATIONS THAT CLAIM  
7 INVENTIONS, AND OUR FIRST LANGUAGE WAS DEVELOPED AND WE  
8 WERE REMINDED THAT A BETTER DESCRIPTION OF THIS WAS  
9 INVENTIONS MADE IN THE PERFORMANCE OF CIRM-FUNDED  
10 RESEARCH. SO WE WOULD PROPOSE THAT WE ALTER THE  
11 DOCUMENT WE GAVE YOU TO INCLUDE THE WORD "MADE" HERE  
12 RATHER THAN "DEVELOPED" IN BOTH 3 AND 4.

13 THEN SIMILARLY, ANY LICENSING AGREEMENTS OF  
14 INVENTIONS MADE IN THE PERFORMANCE OF CIRM-FUNDED  
15 RESEARCH, AND ITEM 5 IS THE SAME UNDER THIS SECTION.

16 SO AT THIS POINT I WOULD LIKE TO OPEN THE  
17 DISCUSSION TO ALL OF YOU IN THE ICOC FIRST AND THEN TO  
18 THE AUDIENCE ABOUT ANY COMMENTS IN SECTION G; AND IF  
19 WE'RE COMFORTABLE WITH SECTION G, I WOULD LIKE A MOTION  
20 TO APPROVE SECTION G. I THINK THE EASIEST WAY FOR US  
21 TO STEP THROUGH THIS IS IN SECTIONS. SO I WOULD LIKE  
22 NOW FOR ANY COMMENTS ANY OF YOU HAVE ON SECTION G OF  
23 PART 2 OF THIS RECOMMENDATION FROM THE WORKING GROUP.

24 MS. SAMUELSON: MAYBE THIS WILL JUST HAPPEN  
25 BY VIRTUE OF THE DISCUSSION, BUT THAT WAS JUST TOO FAST

1 FOR ME, NOT BEING A PART OF THE TASK FORCE AND TRYING  
2 TO FIGURE OUT WHERE IT WAS IN MY MATERIALS. I NEED A  
3 LITTLE MORE -- I WOULD ASK JUST TO HAVE THAT SUMMARY  
4 REPEATED IF THAT'S POSSIBLE. I DON'T WANT TO BELABOR  
5 IT.

6 DR. PENHOET: IF I MIGHT, RETURNING TO THE  
7 FIRST PART, THERE WERE NO CHANGES IN (1) OR (2) UNDER  
8 G, PROPOSED. AND CHANGES IN (3) AND (4) WERE SIMPLY TO  
9 SUBSTITUTE THE WORD "MADE" FOR THE WORD "DEVELOPED."  
10 THOSE ARE THE ONLY CHANGES THAT WE IN THE TASK FORCE  
11 PROPOSED TO MAKE TO WHAT HAS BEEN SUBMITTED TO YOU FOR  
12 YOUR REVIEW IN ADVANCE OF THIS MEETING.

13 MS. SAMUELSON: SO THIS TEXT I'M LOOKING AT,  
14 THERE ARE CHANGES TO THIS THAT ARE BEING RECOMMENDED?

15 DR. PENHOET: THAT'S CORRECT. AND THEY'RE  
16 INDICATED IN RED HERE. THE DOCUMENT THAT YOU WERE  
17 PROVIDED IN ADVANCE OF THE MEETING SAYS THE WORD  
18 "DEVELOPED" RATHER THAN THE WORD "MADE," SO THE LIGHT  
19 GREY IS THE EXISTING LANGUAGE IN THE DOCUMENT PRESENTED  
20 TO YOU FOR YOUR REVIEW. THE WORD "MADE" IS WHAT WE  
21 PROPOSED TO SUBSTITUTE FOR THE WORD "DEVELOPED"; AND AS  
22 WE GO THROUGH THIS, THAT'S THE GENERAL PARADIGM. THANK  
23 YOU FOR CLARIFYING THAT, JOAN.

24 AS YOU WILL SEE GOING FORWARD, WHERE WE NOW  
25 RECOMMEND SOME CHANGES TO WHAT YOU HAVE IN FRONT OF

1 YOU, THOSE WILL BE INDICATED IN RED, AND WHAT'S DELETED  
2 WILL BE INDICATED IN THE LIGHT-COLORED MATERIAL.

3 SO IN THIS SECTION (G)(1) THROUGH (5), THE  
4 ONLY TWO CHANGES WE RECOMMEND TO THE DOCUMENT IN FRONT  
5 OF YOU ARE CHANGING THE WORD "DEVELOP" TO THE WORD  
6 "MADE" IN BOTH ITEMS (3) AND (4). OF COURSE, WE HAVE  
7 THE OPPORTUNITY HERE TO MAKE ANY CHANGES THAT WE SEE  
8 FIT AS A BOARD, BUT THAT'S OUR RECOMMENDATION OF THE  
9 WORKING GROUP FOR SECTION G.

10 SO ANY COMMENTS FROM ANY OF THE BOARD MEMBERS  
11 ON SECTION G? THEN I'D LIKE TO ASK IF THERE ARE  
12 COMMENTS FROM THE PUBLIC ON SECTION G.

13 MR. SIMPSON: JOHN SIMPSON FROM THE  
14 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. IT SEEMED  
15 IT WAS AN APPROPRIATE TIME TO SAY THAT WE WERE VERY  
16 PLEASED WITH THE WAY THE WHOLE PROCESS WAS GOING ON  
17 EARLIER; THAT WE DID, IN FACT, AS THE CHAIRMAN SAID,  
18 HAVE AMPLE OPPORTUNITY TO BE INVOLVED IN THAT PROCESS.  
19 AND IT HASN'T GONE COMPLETELY WHERE WE THINK IT SHOULD,  
20 AND WE'LL HAVE SOME MORE COMMENTS, BUT I DID WANT TO  
21 THANK YOU VERY MUCH, YOU AND THE OTHER MEMBERS OF THE  
22 TASK FORCE, FOR THE TIME THAT YOU SPENT WITH US  
23 THROUGHOUT THIS.

24 DR. PENHOET: THANK YOU FOR YOUR  
25 PARTICIPATION. ANY OTHER COMMENT ON SECTION G? IF

1 NOT, MAY I HAVE A MOTION FROM SOMEONE ON THE ICOC TO  
2 APPROVE SECTION G OF THIS DOCUMENT?

3 DR. PIZZO: SO MOVE.

4 MR. GOLDBERG: SECOND.

5 DR. PENHOET: MOVED PIZZO, SECONDED MICHAEL  
6 GOLDBERG. DO WE NEED A ROLL CALL VOTE, JAMES, OR A  
7 VOICE VOTE?

8 MR. HARRISON: VOICE VOTE.

9 DR. PENHOET: ALL IN FAVOR. OPPOSED? THANK  
10 YOU.

11 NOW THAT WE HAVE THE EASIEST SECTION OUT OF  
12 THE WAY, WE'LL MOVE TO THE MORE DIFFICULT SECTION,  
13 WHICH IS SHARING OF INTELLECTUAL PROPERTY.

14 UNDER SECTION H OF THE DOCUMENT GIVEN TO YOU,  
15 THE FIRST IS PUBLICATION REQUIREMENTS. HERE WE HAVE  
16 GOTTEN SOME INPUT, NONE OF WHICH HAS AFFECTED WHAT WE  
17 HAVE ON (1), (2), OR (3) IN FRONT OF YOU. AND WE HAVE  
18 A PUBLICATION REQUIREMENT THAT CIRM RESEARCH IS  
19 ACKNOWLEDGED. THIS IS A STANDARD FEATURE OF THESE  
20 DOCUMENTS, FOLLOWING GENERALLY NIH MATERIALS.

21 THE SECTION B IS PUBLICATION-RELATED  
22 BIOMEDICAL MATERIALS REQUIREMENTS. THIS IS AN AREA  
23 WHERE WE HAVE HAD A FAIR AMOUNT OF INPUT AND RELATES TO  
24 THE WHOLE GENERAL COMPROMISE THAT WE HAVE REACHED, WE  
25 BELIEVE, IN THIS AREA OF REALLY PUSHING SHARING, AT THE

1 SAME TIME REALIZING IT MAY INHIBIT SOME KINDS OF  
2 ACTIVITIES.

3 SO WHAT YOU HAVE IN FRONT OF YOU IN THIS  
4 (B)(1), IT SAYS THAT GRANTEES SHALL SHARE BIOMEDICAL  
5 MATERIALS DESCRIBED IN A PUBLISHED SCIENTIFIC ARTICLE  
6 FOR RESEARCH PURPOSES WITHIN 60 DAYS OF RECEIPT OF A  
7 REQUEST AND WITHOUT BIAS AS TO THE AFFILIATION OF THE  
8 REQUESTER.

9 UNDER SPECIAL CIRCUMSTANCES, EXTENSIONS MAY  
10 BE POSSIBLE WITH THE APPROVAL OF THE SCIENTIFIC PROGRAM  
11 OFFICER OF CIRM. ALTERNATIVELY, AUTHORS MAY PROVIDE  
12 REQUESTS FOR INFORMATION ON HOW TO RECONSTRUCT OR  
13 OBTAIN THE MATERIAL. MATERIALS ARE TO BE SHARED  
14 WITHOUT COST. UNDER SUCH CIRCUMSTANCES WHERE  
15 SIGNIFICANT EXPENSES ARE REQUIRED TO GENERATE THESE,  
16 THE GRANTEE MAY RECOVER THOSE EXPENSES AND ONLY THOSE  
17 FROM THE REQUESTER AFTER APPROVAL BY THE SCIENTIFIC  
18 PROGRAM OFFICER.

19 THE COMMENTS WHICH HAVE APPEARED UNDER THIS  
20 SECTION REALLY RELATE TO THE ISSUE OF MAKING -- TRYING  
21 TO BE SURE WE DON'T OVERLY BURDEN PEOPLE WHO COME UP  
22 WITH NEW CELL LINES, ETC., AND HENCE THE LANGUAGE ABOUT  
23 IF IT BECOMES A BURDEN, THAT THEY'LL ACTUALLY TEACH  
24 SOMEONE HOW TO DO THIS THEMSELVES BECAUSE SOME REAGENTS  
25 IN WIDESPREAD USE CAN BE EXTREMELY HARD TO PRODUCE.

1 AND WE DON'T WANT TO PLACE THAT BURDEN UNNECESSARILY ON  
2 INVESTIGATORS.

3 THERE HAS BEEN CONCERN -- WELL, AND ALSO,  
4 WITHOUT BIAS TO THE AFFILIATION OF THE REQUESTER.  
5 ELSEWHERE WE POINT OUT THAT THEY SHOULD BE BONA FIDE  
6 RESEARCH INSTITUTIONS WITHIN THE STATE. IT MEANS THAT  
7 THE SHARING WOULD OCCUR WITH BOTH NONPROFIT  
8 ORGANIZATIONS AND WITH FOR-PROFIT ORGANIZATIONS WHO ARE  
9 ENGAGED IN RESEARCH WITHIN THE STATE. MANY OF US  
10 BELIEVE THAT THE RECIPROCITY THERE IS IMPORTANT BECAUSE  
11 WE ARE TRYING TO DRIVE AN EXPECTATION THAT THE PRIVATE  
12 SECTOR ALSO WILL MAKE THEIR MATERIALS AVAILABLE TO THE  
13 NONPROFIT SECTOR. THAT'S A LITTLE BIT OF THE THINKING  
14 BEHIND THIS SECTION.

15 THE NEXT SECTION IS PATENT APPLICATIONS  
16 REQUIREMENTS. GRANTEE ORGANIZATIONS SHALL BEAR  
17 RESPONSIBILITY FOR THE COSTS ASSOCIATED WITH THESE,  
18 THEY'LL REPORT ON AN ANNUAL BASIS SUCH APPLICATIONS  
19 THAT CLAIM INVENTIONS, AGAIN, SUBSTITUTING THE WORD  
20 "MADE" FOR THE WORD "DEVELOPED" IN THE PERFORMANCE OF  
21 CIRM-FUNDED RESEARCH.

22 THIRD ONE, REQUIREMENTS FOR LICENSING. THIS  
23 HAS BEEN A DIFFICULT AREA TO REACH A GOOD COMPROMISE  
24 IN. GRANTEE ORGANIZATIONS SHALL ASSUME RESPONSIBILITY  
25 FOR LICENSING ACTIVITIES, INCLUDING IDENTIFICATION OF

1 POTENTIAL LICENSEES, NEGOTIATION OF LICENSE AGREEMENTS,  
2 AND DOCUMENTATION OF DEVELOPMENT PROGRESS FOR LICENSES  
3 RELATING TO CIRM-FUNDED PATENTED INVENTIONS. GRANTEE  
4 ORGANIZATIONS ARE REQUIRED TO SUBMIT A LICENSING  
5 ACTIVITIES REPORT RELEVANT TO CIRM-FUNDED INVENTIONS ON  
6 AN ANNUAL BASIS.

7 NO. 2, GRANTEE ORGANIZATIONS SHALL NEGOTIATE  
8 NONEXCLUSIVE LICENSES OF THESE INVENTIONS WHENEVER  
9 POSSIBLE. NEVERTHELESS, GRANTEE ORGANIZATIONS MAY  
10 NEGOTIATE AND AWARD EXCLUSIVE LICENSES FOR CIRM-FUNDED  
11 INVENTIONS RELEVANT TO THERAPIES AND DIAGNOSTICS IF  
12 SUCH LICENSES ARE NECESSARY TO PROVIDE ECONOMIC  
13 INCENTIVES REQUIRED TO ENABLE COMMERCIAL DEVELOPMENT  
14 AND AVAILABILITY OF THE INVENTIONS.

15 I'LL STOP THERE. WE'VE HAD A FAIR AMOUNT OF  
16 INPUT THAT HAS ESSENTIALLY POINTED US TO THE FACT THAT  
17 BY RESTRICTING EXCLUSIVE LICENSES TO THERAPIES AND  
18 DIAGNOSTICS, WE'RE SAYING EXCLUSIVE LICENSES WOULD NOT  
19 BE AVAILABLE FOR RESEARCH TOOLS AND OTHER THINGS.  
20 SEVERAL GROUPS HAVE POINTED OUT THAT THIS MAY BE OVERLY  
21 RESTRICTIVE IN THIS AREA, AND THAT WE DON'T WANT TO  
22 COMPLETELY PRECLUDE THE COMMERCIALIZATION OF SOME OF  
23 THESE RESEARCH TOOLS IF THEY'RE GOING TO BE USED ON A  
24 WIDESPREAD BASIS. SO THERE'S AN ISSUE HERE, AND I'M  
25 SURE WE'LL HEAR FROM SOME IN THE AUDIENCE ON THIS

1     ISSUE.

2                   A FURTHER REFINEMENT OF THIS COULD BE THAT WE  
3     WOULD ADD LANGUAGE THAT ANY INVENTION COULD BE SUBJECT  
4     TO EXCLUSIVE LICENSE IF THESE TERMS APPLY; THAT IS,  
5     ESSENTIALLY NO ONE WOULD DEVELOP THE TECHNOLOGY WERE IT  
6     NOT FOR AN EXCLUSIVE LICENSE.  THAT'S SOMETHING FOR  
7     YOUR CONSIDERATION, AND I THINK IT'S BECAUSE WE'VE  
8     GOTTEN A FAIR AMOUNT OF INPUT SINCE THE DOCUMENT WAS  
9     PRODUCED ON SPECIFICALLY THAT ISSUE.  IT MIGHT BE THAT  
10    SUCH EXCLUSIVE LICENSES FOR RESEARCH TOOLS WOULD  
11    REQUIRE THE APPROVAL OF CIRM, FOR EXAMPLE, WOULD BE ONE  
12    ALTERNATIVE TO THAT.  SO LET'S MAKE A NOTE OF THAT  
13    ISSUE AND COME BACK TO IT AS WE DISCUSS THIS.

14                  IN DUE DILIGENCE RELATED TO LICENSEES,  
15    GRANTEE ORGANIZATIONS SHALL DOCUMENT DEVELOPMENT AND  
16    COMMERCIALIZATION CAPABILITIES, THE INTENDED LICENSEE,  
17    AND TERMS ADDRESSING ALL RELEVANT THERAPEUTIC AND  
18    DIAGNOSTIC USES FOR WHICH THE INVENTION IS APPLICABLE.  
19    THIS WAS MEANT TO ADDRESS THE ISSUE OF NOT LEAVING A  
20    NUMBER OF INDICATIONS FALLOW IN AN EXCLUSIVE LICENSE;  
21    THAT IF IT'S USEFUL FOR MANY DIFFERENT DISEASES, IF THE  
22    LICENSEE WAS NOT PURSUING THESE, THAT THERE WOULD BE AN  
23    OPPORTUNITY TO INTERVENE AND TRY TO ADDRESS THAT IN  
24    ANOTHER WAY.

25                  NO. 3, IN THE CASE OF EXCLUSIVE LICENSING



1     AGREEMENTS, GRANTEE ORGANIZATIONS SHALL INCLUDE TERMS  
2     FOR COMMERCIAL DEVELOPMENT PLANS TO BRING THE INVENTION  
3     TO PRACTICAL APPLICATION.  SUCH PROVISIONS SHALL  
4     INCLUDE DEVELOPMENT OF MILESTONES AND BENCHMARKS SO  
5     THAT DEVELOPMENT CAN BE ASSESSED AND MONITORED.  AS YOU  
6     WILL SEE LATER IN THIS DISCUSSION UNDER THE SECTION I,  
7     MARCH-IN RIGHTS, THIS WOULD BE AN AREA WHERE MARCH-IN  
8     RIGHTS COULD CONCEIVABLY BE EXERCISED IF AN EXCLUSIVE  
9     LICENSEE WAS NOT DILIGENTLY PURSUING THE DEVELOPMENT  
10    AND MEETING THE MILESTONES THAT WERE INDICATED IN --  
11    THE MILESTONES INDICATED IN THE LICENSING AGREEMENT  
12    ITSELF.

13                 NO. 4, GRANTEE ORGANIZATIONS SHALL GRANT  
14    EXCLUSIVE LICENSES INVOLVING CIRM-FUNDED PATENTED  
15    INVENTIONS RELEVANT TO THERAPIES AND DIAGNOSTICS TO  
16    ORGANIZATIONS WITH PLANS TO PROVIDE ACCESS TO RESULTANT  
17    THERAPIES FOR UNINSURED CALIFORNIA PATIENTS.  THIS IS A  
18    REQUIREMENT OF EACH LICENSE, THAT THERE IS A PLAN IN  
19    PLACE TO DO THAT.

20                 AFTER MUCH DISCUSSION, WE DECIDED NOT TO TRY  
21    TO DEFINE THIS FURTHER, BUT TO LEAVE IT TO THE  
22    IMAGINATION OF THE COMPANIES WHICH WERE SEEKING  
23    EXCLUSIVE LICENSES, AND THERE ARE MANY DIFFERENT WAYS  
24    THEY CAN ADDRESS THIS, AND, IN FACT, ARE BEING  
25    ADDRESSED IN THE MARKETPLACE TODAY.

1                   IN ADDITION, SUCH LICENSEES WILL AGREE TO  
2    PROVIDE TO PATIENTS WHOSE THERAPIES WILL BE PURCHASED  
3    IN CALIFORNIA BY PUBLIC FUNDS THE THERAPIES AT A COST  
4    NOT TO EXCEED, OUR ORIGINAL LANGUAGE SAID LOWEST  
5    AVAILABLE COMMERCIAL U.S. PRICE. THERE IS A SUGGESTION  
6    OF A CHANGE TO NOT TO EXCEED THE FEDERAL MEDICAID  
7    PRICE. THE INTENTION ALL ALONG, AS A PRACTICAL MATTER,  
8    THE FEDERAL GOVERNMENT IS ALMOST ALWAYS OBTAINING THE  
9    MOST FAVORABLE PRICE BECAUSE THAT'S HOW THEY NEGOTIATE  
10   THESE AGREEMENTS. SO THE INTENT WAS TO ENSURE THAT THE  
11   CALIFORNIA PURCHASERS WERE NOT DISADVANTAGED VIS-A-VIS  
12   THE FEDERAL GOVERNMENT. SO WE PUT IN LOWEST AVAILABLE  
13   COMMERCIAL U.S. PRICE.

14                  IT WAS THEN SUGGESTED TO US BY A COUPLE OF  
15   LEGISLATORS AND BY JOHN SIMPSON THAT PEGGING IT TO  
16   FEDERAL MEDICAID PRICE MAKES IT MORE CLEAR THAT IT'S  
17   REALLY THE LOWEST FEDERAL PRICE. I THINK WE COULD GO  
18   EITHER WAY ON THIS ISSUE. SO THAT'S A SECOND THING FOR  
19   YOU TO KEEP IN MIND IN THIS SECTION, WHAT WE'LL  
20   ACTUALLY PUT HERE IN THIS SECTION.

21                  AND THEN THE CIRM MAY MAKE ACCESS PLANS  
22   AVAILABLE FOR REVIEW BY THE ICOC ON AN ANNUAL BASIS.

23                  THE NEXT SECTION IS ABOUT PATENTED  
24   INVENTIONS. IT'S MOSTLY ABOUT MONITORING. BUT, AGAIN,  
25   PUTTING THE ONUS ON GRANTEE ORGANIZATIONS TO NEGOTIATE

1 RELEVANT AND SPECIFIC GROUNDS FOR MODIFICATION OR  
2 TERMINATION OF LICENSES. EXAMPLE WOULD INCLUDE FAILURE  
3 TO MEET AGREED-UPON COMMERCIAL BENCHMARKS, FAIL TO KEEP  
4 LICENSED INVENTION REASONABLY ACCESSIBLE TO THE PUBLIC  
5 FOR RESEARCH PURPOSES, AND FAILURE TO REASONABLY MEET  
6 AGREED-UPON PLAN FOR ACCESS TO RESULTANT THERAPIES AS  
7 DESCRIBED IN (D)(4) ABOVE. THAT GRANTEE ORGANIZATIONS  
8 SHOULD MONITOR THESE ACTIVITIES AND TAKE THE  
9 ADMINISTRATIVE ACTIONS TO SEE THAT COMPLIANCE IS MET.

10 AND THEN FINALLY, THE RESEARCH EXEMPTION  
11 APPEARS. GRANTEE ORGANIZATIONS AGREE THAT CALIFORNIA  
12 RESEARCH INSTITUTIONS MAY USE THEIR CIRM-FUNDED  
13 PATENTED INVENTIONS FOR RESEARCH PURPOSES AT NO COST.  
14 GRANTEE ORGANIZATIONS, OUR ORIGINAL LANGUAGE SAID SHALL  
15 REQUIRE THE SAME AGREEMENT OF EACH OF THEIR LICENSEES,  
16 AND THE SUBSTITUTE ALTERNATE LANGUAGE COULD BE ENSURE  
17 THAT SUCH USE IS PRESERVED IN THEIR LICENSES OF  
18 CIRM-FUNDED PATENTED INVENTIONS. SO THAT'S A THIRD  
19 AREA WHICH HAS BEEN BROUGHT UP FOR OUR CONSIDERATION  
20 THIS MORNING.

21 FINALLY, REVENUE SHARING REQUIREMENTS.  
22 GRANTEE ORGANIZATIONS SHALL SHARE A FRACTION OF ANY  
23 REVENUES, NOT JUST ROYALTY REVENUES, BECAUSE SOMETIMES  
24 THERE ARE SINGLE PAYMENTS OF OTHER FORMS OF  
25 REMUNERATION THAT COME WITH LICENSING AGREEMENTS THAT

1 ARE NOT JUST ROYALTIES. SO WE'RE TALKING ABOUT ALL  
2 REVENUE SOURCES WITH THE INVENTORS IN ACCORDANCE WITH  
3 THEIR ESTABLISHED POLICIES. ESTABLISHED MEANS  
4 ESTABLISHED PRIOR TO GETTING A CIRM GRANT. SO WE  
5 DELIBERATELY DON'T WANT ORGANIZATIONS TO HAVE A  
6 DIFFERENT POLICY FOR PAYING INVENTORS AS A RESULT OF  
7 CIRM FUNDING THAN THEY HAVE FOR ALL OTHER GRANTS. SO  
8 IT'S JUST ALL OF YOU WHO WERE IN THAT WORLD CAN KEEP  
9 DOING WHAT YOU'RE DOING.

10 THE GRANTEE ORGANIZATION MAY RETAIN A  
11 THRESHOLD AMOUNT OF ITS SHARE OF ANY REVENUES RECEIVED  
12 UNDER A LICENSE AGREEMENT OR AGREEMENTS OF ANY  
13 CIRM-FUNDED PATENTED INVENTION. THEREAFTER THE GRANTEE  
14 ORGANIZATIONS SHALL PAY 25 PERCENT OF ITS SHARE OF SUCH  
15 REVENUES TO THE STATE OF CALIFORNIA FOR DEPOSIT INTO  
16 THE STATE'S GENERAL FUND UNLESS SUCH ACTION VIOLATES  
17 ANY FEDERAL LAW. THE THRESHOLD AMOUNT THAT WE  
18 RECOMMEND IS \$500,000, MULTIPLIED BY A FRACTION THAT  
19 YOU CAN READ THERE. IT'S ALL ABOUT STAYING UP WITH  
20 INFLATION. AND THIS IS AN AREA AROUND WHICH THERE'S  
21 BEEN MUCH DISCUSSION, AS YOU CAN IMAGINE.

22 THE \$500,000 IS A PRECEDENT SET BY A NUMBER  
23 OF OTHER FUNDING ORGANIZATIONS. IT'S MEANT TO DO TWO  
24 THINGS: ALLOW THE UNIVERSITIES TO RECOUP THEIR COSTS  
25 FOR THE SPECIFIC PATENT THAT THEY'RE LICENSING IN THIS

1 CASE. IN ADDITION TO THAT, TO HELP COMPENSATE THEM FOR  
2 THE OTHER PATENTS THAT THEY WOULD FILE UNDER CIRM  
3 FUNDING FOR WHICH THEY WILL NEVER RECEIVE ANY  
4 COMPENSATION. SO IT'S A NUMBER WHICH HAS BEEN USED  
5 TRADITIONALLY IN THIS FIELD, AND IT'S A NUMBER THAT OUR  
6 GROUP THOUGHT WAS REASONABLE, LOOKING AT THE ACTUAL  
7 COSTS UNIVERSITIES INCUR FOR THESE ACTIVITIES, LOOKING  
8 AT THE PRECEDENT SET BY A NUMBER OF OTHER FUNDING  
9 AGENCIES THROUGHOUT THE COUNTRY.

10 THE SENTIMENT OF OUR GROUP, HOWEVER, WAS THAT  
11 IF WE APPROVED THE \$500,000 EXCLUSION, THAT THAT SHOULD  
12 COVER ALL THESE COSTS. AND, THEREFORE, WE'RE TALKING  
13 ABOUT GROSS REVENUES RECEIVED AND NOT NET REVENUES BY  
14 THE UNIVERSITIES, THAT ALL THEIR COSTS WOULD BE BORNE  
15 UNDER THE \$500,000 RULE. ANOTHER AREA WHERE THERE MAY  
16 BE SOME DISCUSSION IN THIS GROUP.

17 AND THEN FINALLY, REVENUE SHARING  
18 REQUIREMENTS. THIS IS JUST A PROPORTIONAL PART. IF  
19 SOMEBODY ELSE HAS FUNDED PART OF THE WORK, THEY DESERVE  
20 PART OF THE REWARD; THEREFORE, IT SHOULD BE  
21 PROPORTIONAL TO THE FUNDING. AND THEN A REQUIREMENT  
22 THAT THE GRANTEE ORGANIZATION'S SHARE OF ANY ROYALTIES  
23 EARNED SUPPORTS SCIENTIFIC RESEARCH AND EDUCATION.

24 AGAIN, THIS IS ONE OF THOSE PARTS. WE HAVE  
25 TRIED AS HARD AS POSSIBLE TO MAKE OUR PROGRAM

1 COMPATIBLE WITH BAYH-DOLE, ALTHOUGH WE THINK WE'VE  
2 PUSHED MANY PARTS OF THIS FURTHER THAN THE BAYH-DOLE  
3 ACTUALLY INDICATES TODAY.

4 THIS IS ABOUT PRESS RELEASES AND MARCH-IN  
5 RIGHTS. WITH THAT, I'LL GO BACK TO THE BEGINNING NOW.

6 THIS WAS AN OVERVIEW OF THE ENTIRE PACKAGE OF  
7 REQUIREMENTS, BUT I NOW WOULD LIKE TO TAKE COMMENTS  
8 FROM, FIRST, THE BOARD AND THEN FROM THE AUDIENCE ON  
9 ANY OF THESE ISSUES. ANY DISCUSSION ABOUT PUBLICATION  
10 REQUIREMENTS FROM EITHER THE BOARD OR THE AUDIENCE? IF  
11 NOT, I'LL MOVE ON TO THE SECOND.

12 DR. POMEROY: I JUST HAVE A CLARIFICATION.  
13 IT SAYS THAT NONEXCLUSIVE LICENSES WOULD SORT OF BE THE  
14 NORM, BUT EXCLUSIVE LICENSES COULD BE CONSIDERED UNDER  
15 CERTAIN CIRCUMSTANCES. WHO AND WHAT IS THE PROCESS FOR  
16 DETERMINING WHERE THAT'S NECESSARY? IS THAT LEFT TO  
17 THE GRANTEE, OR DOES CIRM STAFF HAVE A ROLE IN THAT  
18 PROCESS?

19 DR. PENHOET: THE CURRENT LANGUAGE PUTS AN  
20 AFFIRMATIVE OBLIGATION UPON THE GRANTEE TO SEEK  
21 NONEXCLUSIVE LICENSES AND MAKE THE DECISION ABOUT  
22 WHETHER IT'S POSSIBLE AND MAKE THAT JUDGMENT  
23 ESSENTIALLY ABOUT THE TRADE-OFFS INVOLVED IN EXCLUSIVE  
24 VERSUS NONEXCLUSIVE LICENSING. SO IT'S AN AFFIRMATIVE  
25 OBLIGATION ON THEIR PART TO FOLLOW OUR GUIDELINES, BUT

1 THE FINAL DECISION WOULD BE IN THE HANDS OF THE GRANTEE  
2 IN NEGOTIATING SUCH A LICENSE WITH THE LICENSEE IN THE  
3 CURRENT LANGUAGE OF THE DOCUMENT.

4 DR. POMEROY: JUST TO MAKE SURE I UNDERSTAND.  
5 SO THE GRANTEE WOULD BE THE PERSON WHO WAS DETERMINING  
6 IF AN EXCLUSIVE LICENSE WAS NECESSARY TO PROVIDE  
7 ECONOMIC INCENTIVES REQUIRED TO ENABLE COMMERCIAL  
8 DEVELOPMENT UNDER THIS LANGUAGE?

9 DR. PENHOET: THAT'S CORRECT. IF WE, ON THE  
10 OTHER HAND, ADOPT SOME LANGUAGE ABOUT EXCLUSIVE  
11 LICENSING IN THE CASE OF THINGS WHICH ARE NOT ALL OTHER  
12 THINGS WHICH ARE NOT THERAPIES OR DIAGNOSTICS, IT COULD  
13 BE THAT A CONSERVATIVE MOVE FROM WHERE WE ARE NOW,  
14 WHICH SAYS THOSE WILL ALL BE NONEXCLUSIVE, IF THERE  
15 WERE EXCLUSIVE OPPORTUNITIES, ONE ALTERNATIVE WOULD BE  
16 TO PUT SOME LANGUAGE WHICH WOULD REQUIRE CIRM APPROVAL  
17 BECAUSE CIRM IS A RESEARCH FUNDING AGENCY. SO THAT'S  
18 ONE THOUGHT.

19 DR. BIRGENEAU: I PRESUME THIS IS THE CASE,  
20 BUT I GUESS I WOULD LIKE TO BE AND THE OTHERS TO BE  
21 REASSURED THAT THE POLICIES ARE FULLY COMPATIBLE WITH  
22 BAYH-DOLE SO THAT IN THE EVENT THAT FEDERAL POLICY  
23 CHANGES, THAT INSTITUTIONS WILL BE ABLE TO AND  
24 INVESTIGATORS WILL BE ABLE TO MIX FEDERAL AND STATE  
25 FUNDS.

1 DR. PENHOET: THAT WAS THE INTENT. I THINK,  
2 THOUGH, THAT WE CAN'T ADOPT A POLICY WHICH ANTICIPATES  
3 CHANGES IN THE FEDERAL LAW, SO WE WOULD HAVE TO COME  
4 BACK TO THIS GROUP IF THE FEDERAL LAW IS CHANGED TO  
5 MAKE THAT. I THINK THE ONE AREA THAT YOU UNDOUBTEDLY  
6 SAW WAS THE RETURN TO THE STATE. BAYH-DOLE DOES HAVE A  
7 REQUIREMENT THAT IT BE USED FOR RESEARCH AND EDUCATION,  
8 ANY RETURNS. AND OUR LANGUAGE HAS BOTH THE GENERAL  
9 FUND, MONIES FUNGIBLE, I BELIEVE, THE PEOPLE IN THE  
10 STATE ALWAYS ALLOCATE. THE GENERAL FUND SPENDS A LOT  
11 OF MONEY ON EDUCATION AND RESEARCH, SO I BELIEVE IT  
12 COULD BE SET ASIDE IN THE GENERAL FUND FOR THAT  
13 PURPOSE. BUT THAT'S THE ONE AREA WHERE THERE MIGHT BE  
14 SOME EXISTING CONCERN ABOUT WHAT WE'RE PROPOSING.  
15 THAT'S AT LEAST BEEN IDENTIFIED FOR US.

16 DR. NOVA: THANK YOU. I DO LIKE YOUR  
17 RECOMMENDATION FOR THE MODIFIED LANGUAGE ON EXCLUSIVE  
18 THAT WE JUST DISCUSSED THAT CLAIRE JUST BROUGHT UP.  
19 AND THE SECOND THING IS I'M CONCERNED ABOUT THE FEDERAL  
20 MEDICAID LOWEST AVAILABLE COMMERCIAL U.S. PRICE BECAUSE  
21 I'M JUST AFRAID THAT WILL BE A DISINCENTIVE TO THE  
22 INDUSTRIES LIKE THE DIAGNOSTIC INDUSTRY.

23 DR. PENHOET: THANK YOU FOR YOUR COMMENT. IT  
24 OBVIOUSLY WAS AN AREA OF GREAT DISCUSSION. AND THAT'S  
25 THE COMPROMISE THE GROUP IN THE END VOTED FOR; BUT LIKE



1 ALL THINGS IN HERE, IT'S UP TO FURTHER DISCUSSION.

2 I'D LIKE TO JUST FOCUS ON ONE SECTION AT A  
3 TIME, IF I COULD. THAT WOULD BE GREAT.

4 MR. SHESTACK: SECTION I, PUBLICATION OF  
5 RELATED BIOMEDICAL MATERIAL REQUIREMENTS. DID I HEAR  
6 YOU SAY THIS WOULD BE ONLY IN THE STATE, THAT THIS  
7 APPLIED ONLY TO RESEARCHERS WITHIN CALIFORNIA? BECAUSE  
8 IT ISN'T IN THE LANGUAGE. I JUST WANTED A  
9 CLARIFICATION.

10 DR. PENHOET: AT THE MOMENT IT WAS MEANT ONLY  
11 TO REFER TO THE STATE BECAUSE WE HAVE NO WAY TO  
12 GUARANTEE RECIPROCITY WITH THE REST OF THE WORLD, AND  
13 THERE WAS A LARGE CONCERN ABOUT THE FACT THAT WE WOULD  
14 BE WILLINGLY GIVING ALL THESE MATERIALS TO THE REST OF  
15 THE WORLD WITH NO GUARANTEE THAT THEY WOULD GIVE US  
16 ANYTHING BACK IN RETURN. SO THE WAY THIS IS  
17 CONSTRUCTED, THERE IS AN EXPECTATION THAT ALL CIRM  
18 GRANTEES ENGAGED IN STEM CELLS WOULD BE IN THE SAME  
19 POOL WITHIN THE STATE. WE COULD MAKE IT A GENERAL  
20 REQUIREMENT THAT THIS SHARING IS DONE FOR THE ENTIRE  
21 WORLD, BUT WE HAVE NO GUARANTEE OF RECIPROCITY, SO  
22 THERE WAS CONCERN ABOUT THAT ISSUE.

23 DR. BRYANT: SO CAN WE CLARIFY WHETHER WE'RE  
24 GOING SECTION BY SECTION, OR ARE WE GOING TO JUST  
25 DISCUSS THE WHOLE THING? I PREPARED MYSELF TO GO

1 THROUGH IT ONE AT A TIME.

2 DR. PENHOET: YES. I THINK THAT'S THE ONLY  
3 WAY WE CAN DO THAT. ONLY A FEW OF THESE ARE TIED TO  
4 EACH OTHER. BUT IN GENERAL WE CAN TAKE THESE ONE AT A  
5 TIME, AND THIS SECTION IS REALLY THE HEART OF THE  
6 ISSUES WHERE THERE ARE MANY POINTS OF VIEW EXPRESSED  
7 HERE. SO --

8 MS. SAMUELSON: I'VE GOT A COUPLE OF GENERIC  
9 QUESTIONS. MY QUESTIONS ARE GENERIC AND THEY MAY BE  
10 STUPID, BUT YOU'RE ALWAYS SUPPOSED TO ASK THE STUPID  
11 QUESTIONS, NOT HAVING BEEN A PART OF THIS. I GUESS THE  
12 FIRST IS I'M ASSUMING THAT ONCE THESE POLICIES ARE SET,  
13 THIS IS PERHAPS NOT GOING TO BE ONE OF THE AREAS IN  
14 WHICH WE MAY TWEAK OUR POLICY SETTING DEPENDING ON HOW  
15 THINGS ARE GOING. AND SO THIS IS GOING TO SET IN  
16 MOTION WHETHER THERE'S SUFFICIENT INCENTIVES OR  
17 DISINCENTIVES FOR SCIENTISTS TO BE WORKING ACTIVELY AND  
18 SO ON.

19 IS THAT A CORRECT ASSUMPTION, FIRST OF ALL?

20 DR. PENHOET: FIRST OF ALL, THE NIH REQUIRES  
21 MUCH OF THIS TODAY FOR NIH GRANTEES ABOUT SHARING.  
22 THERE'S BEEN A GENERAL CONCERN ABOUT PUTTING MORE TEETH  
23 INTO IT OR MORE PRESSURE IN THIS AREA. BUT AS JAMES  
24 REMINDED US ALL, WHAT WE'RE DOING TODAY IS STARTING A  
25 270-DAY PROCESS IN WHICH THERE WILL BE PUBLIC HEARINGS

1 AND OTHER OPPORTUNITIES. SO WE ARE NOT -- THIS IS NOT  
2 A FINAL APA REGULATION THAT WE'RE APPROVING TODAY.  
3 THIS IS A SET OF NOW FLESHED-OUT PRINCIPLES UPON WHICH  
4 THE FINAL REGULATIONS WILL BE MADE, BUT THOSE FINAL  
5 RECOMMENDATIONS WILL COME AFTER MORE PUBLIC HEARINGS  
6 AND FURTHER REFINEMENT OF THIS.

7 SO ANY OR ALL OF THIS COULD BE CHANGED DURING  
8 THE 270 DAYS, BUT THIS DOCUMENT IS THE STARTING PLACE  
9 FOR THOSE DISCUSSIONS. THAT'S MY UNDERSTANDING; IS  
10 THAT CORRECT, JAMES?

11 MR. HARRISON: THAT'S CORRECT.

12 MS. SAMUELSON: JUST ONE MORE. SO WITH THAT  
13 PROCESS, WHICH I HAD FORGOTTEN ABOUT, IT'S PROBABLY  
14 SAFE TO ASSUME THAT THOSE WHO DISAGREE WITH TAKING  
15 THESE APPROACHES WILL AIR THEIR DISAGREEMENTS IN SOME  
16 PUBLIC FORUM. SO THOSE OF US WHO ARE LESS FAMILIAR  
17 WITH THE INTRICACIES OF THIS --

18 DR. PENHOET: THESE WILL BE PUBLIC HEARINGS,  
19 AND ANY MEMBER OF THE PUBLIC WILL BE INVITED TO TESTIFY  
20 AT THOSE HEARINGS AND BE HEARD. THAT'S THE -- I THINK  
21 THAT'S THE WHOLE POINT OF THE 270-DAY PROCESS IS A  
22 FURTHER REFINEMENT, BUT YOU NEED A STARTING POINT FOR  
23 THAT DISCUSSION, WHICH IS REALLY WHAT WE HAVE TODAY.  
24 HOWEVER, WHAT WE HOPEFULLY WILL APPROVE TODAY IS THE  
25 INTERIM POLICY WHICH WILL APPLY TO THE TRAINING GRANTS,

1 WHICH WE HOPE TO MAKE VERY SOON. HOWEVER, THIS POLICY  
2 WILL NOT BE CONFINED TO THE TRAINING GRANTS. WHAT  
3 WE'RE PROPOSING IS A GENERAL IP POLICY FOR ALL GRANTS;  
4 HOWEVER, IT WILL HAVE EFFECT FOR THE TRAINING GRANTS  
5 WHICH WE'RE ABOUT TO FUND.

6 MS. SAMUELSON: THANKS.

7 DR. PENHOET: SO IF WE CAN GO THROUGH THIS  
8 PAGE BY PAGE THEN. ARE THERE ANY CONCERNS ABOUT THIS  
9 PAGE? OKAY. ARE THERE ANY CONCERNS ABOUT THIS?  
10 HOPEFULLY NOT.

11 THIS ONE WE HAVE HAD A SIGNIFICANT AMOUNT OF  
12 DISCUSSION. I DO THINK WHAT WE MEANT WAS MATERIALS ARE  
13 TO BE SHARED WITHOUT COST EXCEPT IF THAT CAUSES A  
14 BURDEN, IN WHICH CASE THE CIRM WOULD BE ABLE TO ALLOW  
15 ORGANIZATIONS TO RECOVER THEIR COSTS. AND IF THE  
16 BURDEN IS TOO HIGH, THAT THE INVESTIGATORS CAN SIMPLY  
17 TELL SOMEBODY ELSE HOW TO DO THIS.

18 I NEVER WORRY ABOUT DR. BRYANT'S ABILITY TO  
19 GET MY ATTENTION.

20 DR. BRYANT: I HAVE A COMMENT ABOUT THIS  
21 SECTION. AND IT HAS TO DO WITH NOT LETTING -- WELL, I  
22 WOULD CHANGE THE LANGUAGE TO SIMPLY MATERIALS SHOULD BE  
23 SHARED AT COST. AND THE REASON I SAY THAT IS THAT IT'S  
24 AN INHIBITION FOR PEOPLE, ESPECIALLY IF THEY'VE RUN OUT  
25 OF CIRM FUNDING. HOW ARE THEY GOING TO PAY TO DO THE

1 WORK THAT'S NEEDED TO BE DISTRIBUTED? YOU DON'T WANT  
2 PEOPLE MAKING A PROFIT, BUT THEY NEED TO BE ABLE TO  
3 COVER THEIR COSTS FOR DOING IT.

4 DR. PENHOET: MY PERSONAL OPINION IS THAT'S A  
5 FAIR THING. I THINK WITHOUT COST -- IT COULD BE HARD  
6 TO SET THE BAR ON WHAT'S A BURDEN OR WHAT'S NOT A  
7 BURDEN. THAT'S THE PROPOSAL.

8 DR. FRIEDMAN: IF I CAN KEEP FROM BREAKING  
9 THE MICROPHONE. ED, A COUPLE OF QUESTIONS, PLEASE,  
10 THAT I COULD USE HELP WITH. WHEN YOU SAY SHARE  
11 BIOMEDICAL MATERIALS, YOU OBVIOUSLY MEAN CELL LINES,  
12 CULTURE MEDIA.

13 DR. PENHOET: MONOCLONAL ANTIBODIES.

14 DR. FRIEDMAN: EVERYTHING.

15 DR. PENHOET: YES.

16 DR. FRIEDMAN: AND THINGS THAT ARE INCIDENTAL  
17 TO THE EXPERIMENT AND NOT FUNDED BY CIRM, BUT ARE  
18 CRUCIAL TO THE EXPERIMENT, OR THINGS THAT ARE ONLY  
19 FUNDED -- THESE ARE GOING TO SOUND REALLY DETAILED AND  
20 TECHNICAL, BUT I SHARE THE CONCERNS ABOUT THE -- THERE  
21 HAS TO BE A TEST OF REASONABLENESS HERE. AND I DON'T  
22 HAVE AN ANSWER FOR IT TODAY. I COMMEND YOU ALL FOR  
23 HAVING PUT TOGETHER SUCH A RATIONAL POLICY.

24 AND THE ONLY CONCERNS I HAVE IS I CAN SEE  
25 THIS BECOMING VERY, VERY BURDENSOME AND CONTENTIOUS.

1 IF THESE ARE REAGENTS OR CELL LINES THAT ARE DEVELOPED  
2 FROM CIRM-FUNDED RESEARCH, THAT'S ONE THING. IF AN  
3 INSTITUTION HAS A CULTURE MEDIUM OR A PROBE OR  
4 SOMETHING ELSE, IS THAT ALSO EXPECTED TO BE SHARED?

5 DR. PENHOET: I BELIEVE WE DON'T -- THAT IT  
6 WOULD BE OVERREACHING FOR US TO DEMAND OF ANY GRANTEE  
7 THAT THEY FOLLOW OUR POLICIES FOR ALL THEIR ACTIVITIES.  
8 SO I BELIEVE THE SENSE OF OUR GROUP WAS FOR CIRM-FUNDED  
9 WORK, NOT FOR WORK FUNDED BY OTHERS.

10 DR. FRIEDMAN: I THINK WE REALLY NEED TO  
11 CLARIFY THAT THEN. AND I WOULD ASK -- I'M NOT TRYING  
12 TO WORDSMITH THIS TODAY, BUT I WOULD ASK THAT WE  
13 CLARIFY WHICH THINGS AND WHICH NOT. I ALSO ASK PLEASE,  
14 NOTWITHSTANDING YOUR STATEMENT ABOUT WE EXPECT THIS TO  
15 BE RESEARCH AND FOR-PROFIT INSTITUTIONS IN THE STATE OF  
16 CALIFORNIA, I REALLY THINK THAT HAS TO BE SPECIFIED  
17 WHAT SORT OF RESEARCH INSTITUTIONS. I COULD EASILY SEE  
18 THIS BECOMING, FOR PERFECTLY INNOCENT REASONS, A  
19 BURDENSOME THING. JUNIOR COLLEGES, HIGH SCHOOLS,  
20 PEOPLE WHO ARE JUST INTERESTED IN DOING THE RESEARCH,  
21 BUT ARE NONPROFIT, LEGITIMATE ORGANIZATIONS MAKING  
22 REQUESTS. AND I THINK I UNDERSTAND WHAT YOU INTEND.

23 DR. PENHOET: I THINK WE DO NEED, IT'S BEEN  
24 POINTED OUT TO US, A MORE FULLER DEFINITION OF WHAT THE  
25 WORD "RESEARCH INSTITUTION" WILL MEAN. I THINK THAT

1 WILL ADDRESS YOUR ISSUE.

2 DR. FRIEDMAN: I JUST ASK FOR THOSE TWO  
3 CLARIFICATIONS ON THAT PART. THANK YOU.

4 DR. PENHOET: THE TITLE OF THIS, HOWEVER, IS  
5 "SHARING OF CIRM-FUNDED INTELLECTUAL PROPERTY," SO  
6 THAT'S AN OVERRIDING PRINCIPLE FOR THE ENTIRE SECTION,  
7 NOT AN OBLIGATION ON THE ENTIRE ORGANIZATION.

8 DR. FRIEDMAN: I UNDERSTAND. IT'S JUST THAT  
9 I'VE NEVER SEEN THESE THINGS GO WELL.

10 CHAIRMAN KLEIN: YES. THE DIRECTOR OF THE  
11 OFFICE OF TECHNOLOGY MANAGEMENT OF THE SALK INSTITUTE  
12 HAS SUGGESTED UNDER H(B)(1) THAT IF THE VOLUME OF  
13 REQUESTS BECOMES TOO BURDENSOME FOR THE GRANTEE TO  
14 ACCOMMODATE, THE SPO WOULD CONSIDER ALTERNATIVE  
15 DISTRIBUTION METHODS REQUESTED BY THE GRANTEE. HAS  
16 THAT BEEN CONSIDERED? AND WHAT IS YOUR FEELING ABOUT  
17 THE RESPONSE TO THAT INQUIRY?

18 DR. PENHOET: THE LAST SENTENCE WAS MEANT TO  
19 ADDRESS THAT IN A GENERIC WAY. UNDER SUCH  
20 CIRCUMSTANCES WHERE SIGNIFICANT EXPENSES ARE REQUIRED  
21 TO GENERATE THE MATERIALS, THEY MAY RECOVER THESE  
22 EXPENSES FROM THE REQUESTER AFTER APPROVAL BY THE SPO.  
23 AND LATER ON IN SECTION II WE DO PROVIDE -- WELL,  
24 EARLIER IN THIS SECTION WE DO PROVIDE THAT,  
25 ALTERNATIVELY, THEY CAN ACTUALLY TEACH SOMEONE ELSE HOW

1 TO MAKE THE SAME MATERIAL. SO THEY'RE NOT REQUIRED TO  
2 ESSENTIALLY BEGIN A PROGRAM OF BEING THE SOURCE FOR ALL  
3 THESE MATERIALS BECAUSE THAT CAN BE QUITE BURDENSOME,  
4 ESPECIALLY, FOR EXAMPLE, A BROADLY USEFUL MONOCLONAL  
5 ANTIBODY.

6 IF IT'S NOT COMMERCIALIZED BY ANYONE, AND THE  
7 PEOPLE WHO GENERATE IT HAVE TO PRODUCE THE MONOCLONAL  
8 FOR THE ENTIRE COMMUNITY, THEN THAT WOULD BE AN  
9 UNACCEPTABLE BURDEN. I THINK UNDER THAT CASE, THEY  
10 COULD PROVIDE THE CELL LINE WHICH MAKES THE MONOCLONAL  
11 TO ANOTHER INVESTIGATOR AND SAY PLEASE MAKE YOUR OWN  
12 MONOCLONAL USING THIS CELL LINE.

13 CHAIRMAN KLEIN: SO I HAD INTERPRETED --  
14 FIRST OF ALL, THAT IS EXTREMELY HELPFUL. I HAD  
15 INTERPRETED THE REQUEST TO DEAL MORE WITH THE VOLUME OF  
16 REQUESTS THAN WITH THE COST. AND SO THE QUESTION IS AS  
17 TO THE VOLUME OF REQUESTS, HOW DO YOU FEEL ABOUT  
18 PROVIDING THE ABILITY FOR THE SPO TO CONSIDER  
19 ALTERNATIVE DISTRIBUTION METHODS?

20 DR. PENHOET: IF I COULD REFER YOU TO SECTION  
21 III, PAGE 32, WHICH HAS MORE DETAIL AROUND THIS. WHAT  
22 IT DOES SAY IS OCCASIONALLY THE FREQUENCY OF PRODUCTION  
23 AND/OR DISTRIBUTION OF REQUESTED PUBLICATION-RELATED  
24 MATERIALS PRESENTS A BURDEN TO THE AUTHOR. UNDER SUCH  
25 CONDITIONS, THE SPO MAY WORK WITH THE AUTHOR'S GRANTEE



1 ORGANIZATION TO IDENTIFY OR ESTABLISH A SUPPLIER OR  
2 DISTRIBUTOR TO PROMOTE THE DISSEMINATION OF CIRM-FUNDED  
3 DISCOVERIES TO THE SCIENTIFIC COMMUNITY. IN SUCH CASES  
4 THE GRANTEE ORGANIZATION SHOULD CONTACT THE SPO, ETC.  
5 SO THERE IS SOME LANGUAGE THAT BEGINS TO ADDRESS THAT.

6 CHAIRMAN KLEIN: IT SOUNDS LIKE IT'S  
7 EXTREMELY HELPFUL.

8 DR. PENHOET: PERHAPS NOT PERFECTLY, BUT AT  
9 LEAST SENDS A MESSAGE IN THIS DIRECTION.

10 DR. BRYANT: AT SOME POINT BEFORE WE FINISH  
11 THIS DISCUSSION, I'D LIKE TO MAKE A MOTION TO CHANGE  
12 THE LANGUAGE OF THE LAST SENTENCE IN THIS PARAGRAPH. I  
13 DON'T KNOW IF NOW IS THE RIGHT TIME OR NOT. I WOULD  
14 JUST TAKE OUT THE LAST SENTENCE BEGINNING "MATERIALS  
15 ARE TO BE SHARED WITHOUT" -- THE LAST TWO SENTENCES.  
16 AND JUST HAVE A SENTENCE INSTEAD OF MATERIALS ARE TO BE  
17 SHARED WITHOUT COST, MATERIALS ARE TO BE SHARED AT  
18 COST.

19 DR. PENHOET: WITH THE ADDITION OF THE  
20 AT-COST LANGUAGE, WE NO LONGER NEED THE LAST SENTENCE;  
21 IS THAT YOUR POINT?

22 DR. BRYANT: AND THEN GET RID OF THE LAST  
23 SENTENCE BECAUSE THAT WOULD BE SUBSUMED.

24 DR. PENHOET: OKAY. MELISSA, WE'LL JUST NEED  
25 TO KEEP TRACK OF THAT. IF YOU WILL HIGHLIGHT THAT IN

1 THE GRAY COLOR, AND THAT MEANS IT COULD BE SUBJECT TO  
2 DELETION.

3 DR. KESSLER: DO WE HAVE EASILY ACCESSIBLE  
4 THE BEST PRACTICES THAT THAT'S BASED ON, THAT WE CAN  
5 SEE OTHER LANGUAGE?

6 DR. PENHOET: WE HAVE THE GUIDANCE FROM THE  
7 NIH. WE HAVE THE REPORT FROM THE NATIONAL ACADEMIES OF  
8 SCIENCE, WHICH WAS SPONSORED BY THE NIH AND HEADED BY  
9 SHIRLEY TILGHMAN AND OTHERS, WHICH WE SUPPLIED TO ALL  
10 OF YOU.

11 DR. KESSLER: I GUESS THE QUESTION IS THE  
12 LIST OF SIMILAR KINDS OF PROVISIONS THAT HAVE WORKED,  
13 IN EFFECT, SO WE KNOW THAT THERE'S OPERATIONAL --  
14 WHAT'S THE RIGHT WORD TO SAY --

15 DR. PENHOET: YES, WE DO.

16 DR. KESSLER: IS THERE REAL OPERATIONAL  
17 EXPERIENCE TO THAT? IS THERE LANGUAGE THAT WE KNOW HAS  
18 WORKED IN CERTAIN CIRCUMSTANCES?

19 DR. PENHOET: WELL, THIS GENERAL LANGUAGE,  
20 THE GENERAL OBLIGATION TO SHARE THINGS UPON PUBLICATION  
21 IS A REQUIREMENT OF THE NATIONAL INSTITUTES OF HEALTH.  
22 A LOT OF CONCERN HAS BEEN PAID TO THIS ISSUE BECAUSE  
23 THERE'S A BELIEF IN THE SCIENTIFIC COMMUNITY THAT THE  
24 ADHERENCE TO THIS RULE IS HIGHLY -- WHAT SHALL I  
25 SAY? -- DIFFERENTIATED IN THE SCIENTIFIC COMMUNITY, AND

1     THERE ARE GOOD CITIZENS WHO SHARE AND THERE ARE SOME  
2     SCIENTISTS WHO UNFORTUNATELY HAVE NOT SHARED.

3             THE THRUST OF THE RECENT NATIONAL ACADEMIES  
4     STUDY WAS TO PUSH THE SHARING FURTHER, BUT IT'S SIMPLY  
5     A RECOMMENDATION. WE HAVE HAD, I THINK, AS A CORE  
6     PRINCIPLE HERE THAT WE WANTED TO PUSH THE SHARING OF  
7     INTELLECTUAL PROPERTY.

8             DR. KESSLER: I UNDERSTAND THAT. WHAT I'M  
9     ASKING FOR IS CAN YOU POINT TO LANGUAGE OF AN  
10    ORGANIZATION, A FUNDING AGENCY, WHERE THERE HAS BEEN  
11    EXPERIENCE THAT WE CAN TALK ABOUT WHERE THEY HAVE  
12    ACTUALLY GONE THROUGH LANGUAGE, HAVE MODIFIED IT OVER  
13    THE YEARS, HAVE ADOPTED IT, SO THERE'S A REAL  
14    OPERATIONAL EXPERIENCE THAT WE KNOW THAT AT LEAST IT'S  
15    BEEN TESTED IN THE REAL WORLD? IT'S NOT JUST OUR  
16    ASPIRATIONS.

17            DR. PENHOET: THE ANSWER IS YES AND NO. WE  
18    HAVE REVIEWED AT LEAST 50 DOCUMENTS. THERE ARE  
19    REFERENCES IN THE MATERIALS WE SENT TO YOU TO ALL 50.  
20    I DON'T EXPECT MANY OF YOU TO HAVE READ THEM ALL. MARY  
21    HAS READ THEM ALL. I THINK THE ANSWER TO YOUR QUESTION  
22    IS THERE MAY NOT BE A PRECEDENT FOR WHAT WE'RE DOING  
23    BECAUSE WE ARE PUSHING IT FURTHER THAN THE ESTABLISHED  
24    NORMS. AND I THINK IF YOU WOULD LIKE, DURING THE NEXT  
25    270 DAYS, WE CAN EXAMINE WHETHER WE'RE PUSHING IT

1 BEYOND PRACTICABILITY.

2 THE FEEDBACK WE'VE GOTTEN IS THAT WITH THESE  
3 TWO PIECES OF INFORMATION, FIRST OF ALL, THAT  
4 SCIENTISTS DON'T HAVE TO DO ALL OF THIS WORK  
5 THEMSELVES. THEY CAN EMPOWER SOMEBODY ELSE TO DO IT BY  
6 PROVIDING THE KNOW-HOW ESSENTIALLY AND THAT THEY AT  
7 LEAST CAN RECOVER THEIR COST HAS SATISFIED THE CONCERNS  
8 OF MOST OF THE SCIENTIST COMMUNITY THAT WE'VE SPOKEN  
9 WITH.

10 DR. KESSLER: ON THE OTHER HAND,  
11 PROMULGATING, IN ESSENCE, A REGULATION WHEN THERE'S NOT  
12 AN EXPERIENTIAL BASE, WHERE IT'S NOT BEEN TESTED, YOU  
13 HAVE TO BE ABLE THEN TO MAKE CERTAIN PROVISIONS AT  
14 LEAST FOR -- YOU HAVE TO ACKNOWLEDGE UP FRONT THIS HAS  
15 NOT BEEN TESTED, WE DON'T KNOW WHETHER THIS IS GOING TO  
16 WORK. THIS IS WHERE WE ARE. AT LEAST YOU WOULD WANT  
17 TO BUILD IN REVIEW THAT'S MANDATED INTO THIS SO YOU  
18 KNOW WHETHER, IN FACT, THIS WILL WORK IN THE REAL WORLD  
19 IF WE'RE REALLY BLAZING NEW TERRITORY.

20 DR. PENHOET: YOUR POINT IS WELL TAKEN. AND  
21 I GUESS THAT THE CONSEQUENCES OF DEMANDING A REAL WORLD  
22 WORKING EXAMPLE WOULD BE THAT WE WOULD NOT BE ABLE TO  
23 PLOW ANY NEW TERRITORY HERE.

24 DR. KESSLER: IF WE DON'T HAVE THAT REAL  
25 WORLD EXAMPLE AND WE UNDERSTAND THAT, AND WE'RE

1 CRAFTING NEW BOUNDARIES HERE, THEN I THINK WE HAVE AN  
2 OBLIGATION NOT TO PUT INTO STONE SOMETHING BY  
3 REGULATION. WE HAVE TO SOME WAY HAVE A MECHANISM WHEN  
4 WE'RE CRAFTING NEW TERRITORY AND ALLOW THIS TO HAVE  
5 SOME FLEXIBILITY TO BE MODIFIED OTHER THAN IN THE  
6 NORMAL COURSE OF REGULATION. ONE DOESN'T REGULATE DE  
7 NOVO WITHOUT ANY EXPERIENCE, I GUESS.

8 DR. HALL: I THINK THE FINE LINE WE'RE  
9 WALKING HERE, DAVID, IS HOW TO WRITE IT IN SUCH A WAY  
10 THAT WE ACCOMPLISH THE GOAL OF SHARING ON A REASONABLE  
11 BASIS. I THINK WE CAN ALL THINK OF EXEMPTIONS WHERE  
12 THIS PUTS A BURDEN ON THE INVESTIGATOR, WHERE IT MAY BE  
13 DIFFICULT, AND IT'S HARD TO FIND THAT PRECISE LANGUAGE.  
14 ONE POSSIBILITY WOULD BE TO PUT IN SOMETHING BY WHICH  
15 CIRM OR PROGRAM OFFICER MIGHT MAKE A JUDGMENT ABOUT  
16 WHETHER SOMETHING IS REASONABLE OR NOT. THERE WHAT  
17 HAPPENS IS WE RUN INTO OAL. AND IF WE'RE GOING TO MAKE  
18 THOSE JUDGMENTS, THEN WE HAVE TO CAREFULLY SPECIFY ON  
19 WHAT GROUNDS THEY'LL BE MADE.

20 I THINK WE COULD PROBABLY DO THAT, AND MY  
21 SUGGESTION WOULD BE IN THE 270 DAYS WE HAVE, THAT WE  
22 WORK ON TRYING TO COME UP WITH A MECHANISM, AS I HEAR  
23 THE DISCUSSION, THAT WHERE THIS IMPOSES AN UNREASONABLE  
24 BURDEN, THERE'S SOME MECHANISM FOR STEPPING IN AND  
25 SAYING WE REALIZE YOU MADE THIS ANTISERUM FROM THIS

1 RABBIT. YOU'VE GOT ONLY ONE MILLILITER LEFT AND YOU  
2 CAN'T GIVE IT OUT TO ALL THE WORLD OR YOU WON'T HAVE  
3 ANY TO USE FOR YOUR OWN EXPERIMENTS, WHATEVER IT IS.  
4 WE CAN'T ANTICIPATE ALL THESE THINGS.

5 DR. KESSLER: THAT, I THINK, IS EXACTLY TO  
6 THE ISSUE. THIS, AS IT CURRENTLY READS, DOESN'T REALLY  
7 USE THE REASONABLE -- THERE'S NOT A REASONABLE LANGUAGE  
8 IN THIS.

9 DR. HALL: THE QUESTION IS HOW TO PUT THAT IN  
10 SUCH A WAY THAT IT WILL BE ACCEPTABLE AS A REGULATION.

11 DR. KESSLER: THAT'S THE FIRST POINT.

12 DR. HALL: I WOULD SUGGEST WE WORK ON THAT  
13 DURING THE 270 DAYS IF THAT'S AGREEABLE.

14 DR. KESSLER: SO I THINK WE HAVE THE  
15 REASONABLE LANGUAGE, BUT I ALSO THINK THERE'S ANOTHER  
16 POINT, AND I DON'T KNOW WHAT COUNSEL THINKS. THE  
17 QUESTION IS HOW DO YOU -- THE LAST THING WE WANT IS TO  
18 PUT SOMETHING IN AND CODIFY IT AND IT TURNS OUT NOT TO  
19 WORK AND REMAINS ON THE BOOK, AND WE HAVE GOOD CITIZENS  
20 AND BAD CITIZENS AND IT'S REALLY NOT MEANINGFUL. I  
21 GUESS THE QUESTION IS HOW IN THE RIGHT REGULATORY  
22 FORMAT CAN YOU HAVE REVIEW BUILT IN AND SOME  
23 FLEXIBILITY. MAYBE THAT REASONABLENESS TEST HAS TO BE  
24 WORKED OUT. MAYBE YOU HAVE TO CODIFY CERTAIN GROUPS A  
25 CERTAIN WAY TO DO THIS. I DON'T KNOW HOW TO DO IT ON

1 THE SPOT. THIS IS SOMETHING THAT'S GOING TO HAVE TO  
2 EVOLVE, AND HOW DO WE ALLOW THIS TO EVOLVE IN A  
3 REGULATORY PROCESS, I GUESS, IS MY QUESTION.

4 DR. PENHOET: ONE FIX COULD BE UNDER SPECIAL  
5 CIRCUMSTANCES WHERE SUCH REQUESTS IMPOSE AN  
6 UNREASONABLE BURDEN ON AN INVESTIGATOR, CONTINUE IT ON.  
7 SO YOU COULD ADD THAT PARENTHETICAL PHRASE IN THE  
8 MIDDLE OF THAT SENTENCE.

9 DR. HALL: WHO DECIDES THAT?

10 DR. PENHOET: CIRM.

11 DR. KESSLER: I'M NOT SURE IN THE REGULATIONS  
12 IT ULTIMATELY IS CIRM. YOU HAVE TO SAY WHO WOULD HAVE  
13 THE BURDEN, OTHERWISE --

14 DR. PENHOET: CIRM IS A STATE AGENCY AND IS  
15 RESPONSIBLE FOR THE --

16 DR. KESSLER: BUT THEN YOU HAVE -- I WOULD  
17 ARGUE YOU WOULD HAVE TO SPECIFY THAT IN THE  
18 REGULATIONS.

19 MR. HARRISON: THAT'S RIGHT. IF YOU'RE GOING  
20 TO GIVE THE CIRM A ROLE IN MAKING A DETERMINATION ABOUT  
21 THE REASONABLENESS OF SHARING UNDER CERTAIN  
22 CIRCUMSTANCES, YOU'RE GOING TO HAVE TO PROVIDE  
23 SUFFICIENT CRITERIA SO THAT IT'S CLEAR UPON WHAT BASIS  
24 CIRM IS BEING ASKED TO MAKE THAT DETERMINATION.

25 TO RESPOND TO YOUR SECOND QUESTION, THOUGH,

1     YOU AS A BOARD HAVE THE ABILITY TO AMEND THESE  
2     REGULATIONS AT ANY TIME.  AND YOU COULD MAKE A  
3     DETERMINATION THAT THESE REGULATIONS SHALL BE SUBJECT  
4     TO AN ANNUAL REVIEW OR SOMETHING EVEN MORE FREQUENT IF  
5     YOU DESIRE, BUT THAT IS WITHIN THE SCOPE OF YOUR  
6     AUTHORITY.

7             DR. KESSLER:  DO WE THEN HAVE TO GO THROUGH A  
8     NOTICE AND TIMING OF 270?

9             MR. HARRISON:  NO.  FIRST OF ALL, UNDER  
10    CERTAIN CIRCUMSTANCES, YOU HAVE THE ABILITY TO ADOPT  
11    EMERGENCY REGULATIONS.  BUT ONCE THESE ARE REGULATIONS,  
12    YOU ARE NO LONGER SUBJECT TO THE PROPOSITION 71 CLOCK  
13    WHICH GRANTS AN ELONGATED TIME FOR PUBLIC COMMENT.  
14    YOU'RE SUBJECT TO THE NORMAL ADMINISTRATIVE PROCEDURE  
15    ACT CLOCK, WHICH IS 120 DAYS RATHER THAN 270.  SO  
16    YOU'RE RIGHT.  THERE'S STILL SOME TIME THAT IT WILL  
17    TAKE TO GO THROUGH THE PROCESS OF FORMAL CHANGES TO  
18    THESE REGULATIONS ONCE THEY'RE ADOPTED, BUT THERE IS A  
19    PROCESSES AVAILABLE.

20            DR. KESSLER:  I WAS TALKING TO THE -- I THINK  
21    ZACH'S POINT ON PUTTING IN SOME OF THAT REASONABLE  
22    LANGUAGE AND GIVING SOME CRITERIA AND SPECIFYING THE  
23    CIRM WILL PLAY THAT ROLE MAY BE A BENEFICIAL THING.

24            DR. PENHOET:  WE HAVE SOME --

25            DR. JENNINGS:  WOULDN'T IT BE A GOOD IDEA TO



1     WRITE INTO THE, ALONG THESE LINES, WRITE INTO THIS  
2     PARAGRAPH ITSELF THAT EXEMPTIONS OF THIS GENERAL POLICY  
3     WILL BE APPROVED, HAVE TO BE APPROVED BY XX, WHATEVER  
4     BODY IT IS, SO YOU HAVE RIGHT IN THIS PARAGRAPH ITSELF  
5     AN AVENUE TO THE KIND OF EXCEPTIONS WE EXPECT WHEN  
6     PLOWING NEW GROUND AND A MECHANISM BY WHICH THEY'D BE  
7     DECIDED.

8             DR. PENHOET:  THAT WOULD BE AN EASY FIX.  WE  
9     COULD JUST DELETE EXTENSIONS BEYOND 60 DAYS AND SIMPLY  
10    SAY UNDER SPECIAL CIRCUMSTANCES EXCEPTIONS TO THIS  
11    POLICY -- EXCEPTIONS TO THE ABOVE MAY BE POSSIBLE WITH  
12    THE APPROVAL OF CIRM.  THAT'S AN EASY FIX.

13            DR. PENHOET:  ED HOLMES.

14            DR. HOLMES:  MINE WAS ALREADY ADDRESSED.  
15    THANK YOU.

16            DR. STEWARD:  I GUESS THE QUESTION IS THESE  
17    KINDS OF THINGS DO EXIST IN OTHER FORMS.  AND AS YOU'VE  
18    SAID, THEY ARE HONORED BY SOME AND NOT BY OTHERS.  
19    REALLY THE QUESTION IS, AND THIS IS WHERE THE RUBBER  
20    HITS THE ROAD, I GUESS, IN TERMS OF WHAT CIRM'S ROLE  
21    WOULD BE, WHAT ARE THE PENALTIES FOR FAILURE TO COMPLY?

22            DR. HALL:  WE'LL DISCUSS THAT LATER IN THE  
23    AFTERNOON WITH THE GRANTS ADMINISTRATION POLICY.  
24    THAT'S WHY OUR ENFORCEMENT ON ALL THE ISSUES THAT WE'RE  
25    TALKING ABOUT HERE IN THE MEDICAL AND ETHICAL STANDARDS

1 COME BECAUSE BOTH THE IP POLICY AND MEDICAL AND ETHICAL  
2 STANDARDS WILL BE INCORPORATED AS PART OF OUR GENERAL  
3 GRANTS ADMINISTRATION POLICY THAT EVERYBODY HAS TO  
4 FOLLOW. THEN WE SAY IF YOU DON'T FOLLOW THIS, WE HAVE  
5 A SERIES OF PENALTIES.

6 DR. STEWARD: SO IN THAT SENSE, ALREADY CIRM  
7 IS IN THE BUSINESS OF REVIEWING COMPLIANCE. AND SO WE  
8 PROBABLY REALLY DON'T NEED TO HAVE ANY OTHER LANGUAGE  
9 HERE ABOUT EXCEPTIONS OR REVIEW OR ANYTHING ELSE, DO  
10 WE? I THINK THAT REALLY COVERS IT.

11 DR. PENHOET: CIRM CAN'T ACT -- CIRM HAS  
12 DISCRETION ABOUT ENFORCEMENT, BUT CIRM DOES NOT HAVE  
13 DISCRETION ABOUT MAKING POLICY. WHATEVER IS WRITTEN  
14 HERE WILL GUIDE CIRM IN THE WAY THEY CARRY OUT THIS  
15 POLICY. CIRM'S JOB IS TO CARRY OUT THE POLICY, NOT TO  
16 GENERATE POLICY. SO THEY'LL HAVE TO FOLLOW THESE  
17 REGULATIONS.

18 DR. STEWARD: ALL I WAS SAYING IS I DON'T  
19 THINK THERE'S ANY NEED FOR SORT OF A GENERIC EXCEPTIONS  
20 MAY BE GRANTED BECAUSE BASICALLY IT IS THE REVIEW  
21 PROCESS THAT WOULD DETERMINE WHETHER THERE WAS  
22 COMPLIANCE OR NOT.

23 DR. HALL: I SUGGEST THAT FOR NOW WE PUT IN  
24 EXCEPTIONS MAY BE GRANTED. IN THE 270 DAYS WE WORK, AS  
25 DR. KESSLER SUGGESTED, ON CRAFTING LANGUAGE THAT WOULD

1 PROVIDE HOW WE'RE GOING TO DO THAT. I THINK WE COULD  
2 COME UP WITH SOME LANGUAGE THAT WE COULD USE, BUT, AS  
3 ED PENHOET SAYS, WE CAN'T JUST UNILATERALLY SAY, WELL,  
4 WE THINK YOU VIOLATED THE STANDARD HERE UNLESS IT'S  
5 CLEAR WHAT THE STANDARD IS AND WE HAVE A WAY TO JUDGE  
6 IT.

7 CHAIRMAN KLEIN: YES. IN TERMS OF  
8 DR. KESSLER'S COMMENTS ABOUT THE FACT THAT WE'RE TRYING  
9 TO REACH POTENTIALLY BEYOND THE BASE OF DOCUMENTED  
10 EXPERIENCE, WE COULD BROADCAST EFFECTIVELY TO THE  
11 RESEARCH COMMUNITY IN CALIFORNIA THAT WE ARE GOING TO  
12 CONSIDER EVIDENCE AND RESPOND TO EVIDENCE AS IT COMES  
13 IN TO MAKE SURE THESE ARE FUNCTIONAL FOR THE PURPOSES  
14 OF RESEARCH AND ADVANCING THERAPIES, BUT SIMPLY SAYING  
15 THAT WITHIN 24 MONTHS, BASED UPON THE NEEDS OF THE  
16 RESEARCH COMMUNITY AND ADVANCING THERAPIES, IN LINE  
17 WITH THE MISSION OF THE INSTITUTE, THAT CIRM WILL  
18 REVIEW THESE STANDARDS TO OPTIMIZE THE FUNCTION AND  
19 IMPLEMENTATION. SO THEY WOULD KNOW THEY'RE NOT  
20 BURDENED LONG-TERM, BUT WE'RE GOING TO LOOK AT REAL  
21 PERFORMANCE AND THEY'LL KNOW IT'S A REASONABLE TIME  
22 FRAME WE'RE GOING TO COME BACK AND LOOK AT THE SUBJECT.

23 DR. REED: I GUESS FOLLOWING UP FROM  
24 MR. KLEIN'S SUGGESTION, I THINK ONE WAY, A COUPLE IDEAS  
25 FOR HOW TO GIVE, I THINK, SUFFICIENT FLEXIBILITY WOULD

1 BE TO INSERT LANGUAGE IN THE FIRST SENTENCE THAT SAID  
2 SOMETHING LIKE GRANTEES SHALL MAKE REASONABLE EFFORTS  
3 TO SHARE BIOMEDICAL MATERIALS SO THAT ONE IS NOT  
4 OBLIGATED IF IT TAKES HEROIC EFFORTS OR YOU HAVE  
5 SPECIAL CIRCUMSTANCES WHERE IT WOULDN'T BE REASONABLE  
6 SUCH AS THE EXAMPLE ZACH JUST GAVE.

7 DR. HALL: YOU HAVE TO SAY WHAT REASONABLE IS  
8 IS THE PROBLEM FOR OAL.

9 DR. REED: I THINK ACTUALLY IN SOME OF THESE  
10 IT'S GOOD TO HAVE SOME VAGUENESS IN THE LANGUAGE  
11 BECAUSE IT'S IMPOSSIBLE TO IMAGINE EVERY SCENARIO. SO  
12 THERE ARE TIMES WHEN I THINK IN REGULATIONS IT'S  
13 GOOD --

14 DR. HALL: WE DON'T DISAGREE.

15 DR. REED: -- TO HAVE SOME VAGUENESS AND  
16 OTHER TIMES WHEN I THINK THAT'S A PROBLEM. HERE'S A  
17 CASE WHERE I ACTUALLY THINK IT'S WORKS TO OUR BENEFIT.

18 DR. HALL: WE DON'T DISAGREE. TO MEET THE  
19 STANDARD OF OAL, THAT'S OUR PROBLEM, HOW TO PUT IN  
20 SOMETHING AT THE SAME TIME BE SPECIFIC ENOUGH TO MEET  
21 THEIR STANDARD. THAT'S OUR PROBLEM.

22 DR. REED: THE FURTHER THING I WOULD SUGGEST  
23 IS PERHAPS ADDING A SENTENCE AT THE END OF THIS THAT  
24 SAYS SOMETHING LIKE GRANTEES MAY REQUEST FROM CIRM  
25 ALTERNATIVE SOLUTIONS TO REAGENT DISTRIBUTION TO BE

1     NEGOTIATED IN GOOD FAITH BY BOTH PARTIES BECAUSE THERE  
2     WILL BE TIMES CERTAIN REAGENTS ARE BEST DISTRIBUTED BY  
3     A COMPANY AND NOT BY LABS DOING HOME-BREWED STUFF THAT  
4     REALLY DOESN'T SERVE THE NEEDS OF THE RESEARCH  
5     COMMUNITY.

6             DR. PENHOET:  I BELIEVE, AS I INDICATED  
7     BEFORE, THAT PRECISE LANGUAGE IS PRESENT ON PAGE 32 IN  
8     THE POLICY SECTION.  MANY OF THE EMBELLISHMENTS THAT  
9     YOU'RE TALKING ABOUT TODAY WILL BE IN POLICY.  WE'RE  
10    TALKING ABOUT THE CORE PRINCIPLES HERE THAT WILL BE THE  
11    SOURCE OF THE APA REGULATIONS.  HE MADE A SUGGESTION  
12    ABOUT A REASONABLE EFFORT.  THIS IS A HARD REQUIREMENT.  
13    I DON'T KNOW IF WE CAN VOTE ON EVERY SENTENCE IN THIS  
14    THING, BUT JOHN --

15            DR. REED:  I'D BE HAPPY TO MAKE IT AS A  
16    MOTION IF YOU THINK THAT'S THE WAY TO PROCEED.  WE  
17    MIGHT WANT TO SEE WHAT OTHER INPUT IS NEEDED AND DO IT  
18    ALL IN ONE MOTION, THOUGH, JUST FOR EXPEDIENCY.

19            DR. KESSLER:  AGAIN, THIS MAY ACTUALLY BE  
20    BETTER NOT DONE RIGHT HERE.  I THINK REASONABLENESS,  
21    AGAIN, I THINK WE WOULD HAVE -- REASONABLENESS ENTAILS  
22    BALANCING.  BALANCING IS FINE, BUT WE'D HAVE TO LIST  
23    THOSE FACTORS TO GET BALANCE.  I THINK WE CAN DO OFF  
24    THE TOP OF OUR HEADS SOME OF THEM.  YOU CAN'T JUST PUT  
25    REASONABLE WITHOUT PUTTING WHAT THE BALANCING FACTORS

1 ARE. OBVIOUSLY IT'S COST, IT'S AVAILABILITY, IT'S  
2 IMPEDIMENTS TO RESEARCH. I MEAN IT'S THE NEED FOR THE  
3 MATERIALS. WE CAN GO THROUGH THE WHOLE LIST. BUT,  
4 AGAIN, I THINK THAT'S -- IT NEEDS TO BE WORKED OUT.

5 DR. PENHOET: DR. PRIETO.

6 DR. PRIETO: CONSIDERING THAT THESE ARE  
7 REGULATIONS THAT HAVE TO BE REGULATORY LANGUAGE, I  
8 WOULD BE VERY HESITANT TO PUT IN WORDS LIKE  
9 REASONABLENESS AND JUDGMENT. I THINK THE SUGGESTION  
10 THAT WAS MADE EARLIER, THAT EXEMPTIONS MAY BE GRANTED  
11 BY THE CIRM WITH SPECIFIC CRITERIA FOR THOSE EXEMPTIONS  
12 THAT COULD BE DEVELOPED WITHIN THE 270-DAY PERIOD IS  
13 PROBABLY THE BEST AND -- THE BEST WAY TO GO AND THE WAY  
14 THAT WOULD PASS LEGAL MUSTER.

15 DR. PENHOET: ANY OTHER COMMENTS AT THIS  
16 POINT?

17 MR. SERRANO-SEWELL: VERY BRIEFLY. ON  
18 DR. KESSLER'S POINT ABOUT THIS REASONABLENESS CRITERIA  
19 TEST, I THINK THAT'S ALL FINE AND WELL, AND IT'S  
20 SOMETHING WE CAN WORK ON. IF I UNDERSTOOD DR. HALL'S  
21 COMMENTS, I THINK THIS BOARD SHOULD ADOPT SOMETHING  
22 TODAY WITH THE IDEA THAT WE'LL MAKE ADJUSTMENTS DOWN  
23 THE ROAD. I DON'T SEE ANY BIG IMPEDIMENTS RIGHT NOW,  
24 BUT THIS DOES REPRESENT SOME VERY HARD WORK, EXHAUSTIVE  
25 REVIEW OF EXISTING DOCUMENTS THAT OTHER INSTITUTIONS

1 ARE USING. AND I JUST HAVE THE BELIEF THAT THIS IS  
2 SOME SOLID LANGUAGE AND SOMETHING WE NEED TO GET  
3 BEHIND.

4 DR. PENHOET: OKAY. ANY OTHER COMMENTS?

5 DR. PIZZO: WE DID VERY WELL AT CHANGING THE  
6 DEVELOP TO MADE. I THINK WE'RE GETTING INTO THE  
7 CHALLENGES NOW AND WE GET INTO MORE DETAILS, BUT I  
8 AGREE WITH THE LAST COMMENTS, THAT THERE'S BEEN A LOT  
9 OF WORK DONE BY THE COMMITTEE. IF WE TRY TO REALLY  
10 DEAL WITH ALL THE ISSUES, OF COURSE, WE HAVE TO AND TRY  
11 AND FINALIZE THEM TODAY, WE'RE NOT GOING TO GET BEYOND  
12 THE MARK. I THINK WE'VE GOT TIME, AND THIS IS A VERY  
13 GOOD STARTING POINT.

14 DR. PENHOET: WELL, I BELIEVE IN MY ROLE AS  
15 CHAIR OF THIS SUBCOMMITTEE, THE TASK FORCE, THAT IT WAS  
16 THE SENSE OF THE TASK FORCE THAT WE WANTED TO PUT MORE  
17 TEETH IN THE SHARING POLICY HERE THAN IS COMMONLY  
18 PRACTICED BY NIH GRANTEES. SO THAT WAS ONE OF THE  
19 PRINCIPLES THAT WE DECIDED UPON IN THE GROUP. I DO  
20 BELIEVE THAT THE, MY PERSONAL VIEW, IS THAT THE  
21 MODIFICATIONS WE JUST MADE ARE HELPFUL TO THIS. I  
22 WOULD SUPPORT THEM, BUT THAT'S UP TO THE REST OF YOU.

23 WAS THAT A MOTION FOR APPROVAL OF THIS  
24 LANGUAGE AS MODIFIED, DAVID?

25 MR. SERRANO-SEWELL: SO MOVED.

1 DR. PENHOET: I WON'T CALL FOR A VOTE UNTIL  
2 WE HAVE PUBLIC COMMENT.

3 CHAIRMAN KLEIN: THERE'S A SECOND ON THIS  
4 MOTION.

5 MR. SHEEHY: SECOND.

6 DR. PRIETO: I JUST HAD A QUESTION. DOES  
7 THIS INCORPORATE THE CHANGES DISCUSSED EARLIER, SUCH AS  
8 THE CHANGE TO THE WORD FROM "DEVELOP" TO "MADE" AND THE  
9 OTHER CHANGES?

10 DR. PENHOET: YES. WE VOTED THAT SECTION  
11 ALREADY. WE'RE NOW IN SECTION H(B)(1). I DON'T KNOW  
12 HOW FINELY WE CAN TITRATE THIS GOING FORWARD.

13 DR. POMEROY: ONE ADDITIONAL CLARIFICATION OF  
14 THE MOTION THAT'S BEING DISCUSSED. DOES THIS INCLUDE A  
15 CHANGE TO DR. BRYANT'S SUGGESTION OF CHANGING IT TO AT  
16 COST?

17 DR. PENHOET: THE LANGUAGE IN RED IS THE  
18 CURRENT PROPOSED LANGUAGE.

19 DR. POMEROY: THANK YOU.

20 MR. SHEEHY: ED, THIS APPROVAL WILL INCLUDE  
21 H(A) AS WELL AS H(B)?

22 DR. PENHOET: THAT'S CORRECT.

23 MR. REED: DON REED. I WONDER ABOUT THE  
24 WORDS "AND ONLY THOSE" IN THAT LAST SENTENCE. I'M  
25 THINKING PARTICULARLY ABOUT THE TIME THAT RESEARCHERS



1 MAY HAVE TO TAKE TO ANSWER ALL THESE REQUESTS. I HAVE,  
2 AS A WRITER OF CHILDREN'S BOOKS, I HAVE RECEIVED  
3 ENVELOPES FROM TEACHERS CONTAINING 150 STUDENT LETTERS,  
4 EACH REQUIRING A SEPARATE ANSWER. AND I'M THINKING  
5 ABOUT WHOEVER IS GOING TO HAVE TO DO ALL THIS  
6 ANSWERING. THAT'S A LOT OF TIME. SO I WOULD WONDER IF  
7 A REASONABLE COMPENSATION FOR TIME FOR THE PEOPLE DOING  
8 THIS WORK SHOULD BE INCLUDED. SO YOU COULD JUST REMOVE  
9 THE AND ONLY THOSE AND LEAVE IT TO RECOVER EXPENSES.  
10 TIME IS AN EXPENSE.

11 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
12 CALIFORNIA. ONE SUGGESTION WITH THE AT COST, THERE ARE  
13 SOME RESEARCHERS WHO WOULD PREFER TO SHARE THEIR  
14 MATERIALS AT NO COST. AND THAT SHOULD BE AN OPTION.  
15 SOMETIMES THE RECOVERY OF COST CAN BE A BURDEN ALSO.  
16 MAYBE THAT SHOULD BE A MAXIMUM.

17 THE OTHER COMMENT IS WE KEEP REFERRING BACK  
18 TO THE LANGUAGE IN SECTION III, WHICH IS GOOD LANGUAGE,  
19 BUT SECTION III IS POLICY, AND THIS IS REGULATION. AND  
20 IF THERE'S A DIFFERENCE, THE REGULATION IS GOING TO  
21 PREVAIL, SO MAYBE WE NEED TO BRING THAT LANGUAGE INTO  
22 SECTION II.

23 MR. GOSWAMI: JOYDEEP GOSWAMI. I HEAD UP THE  
24 REGENERATIVE MEDICINE AND STEM CELL BUSINESS UNIT AT  
25 INVITROGEN. WANTED TO ACTUALLY MAKE A COUPLE OF

1 COMMENTS AND, FIRST OF ALL, CONGRATULATE THE COMMITTEE  
2 FOR COMING UP WITH SUCH A COMPREHENSIVE LIST OF IDEAS  
3 AND RULES.

4 THIS PARTICULAR SECTION, I THINK, FROM THE  
5 POINT OF VIEW OF THE RESEARCH TOOLS INDUSTRY, WE HAVE  
6 TWO SPECIFIC CONCERNS. THE FIRST ONE, AND SOMEBODY  
7 ASKED FOR PRECEDENT EARLIER IN THIS DISCUSSION, I WOULD  
8 SAY 90 PERCENT OF THE TOOLS THAT ARE DISTRIBUTED AND  
9 INVENTIONS THAT ARE DISTRIBUTED AMONGST THE ENTIRE  
10 RESEARCH COMMUNITY ARE ACTUALLY DONE BY THE TOOL  
11 INDUSTRY NOT BY INDIVIDUAL RESEARCHERS DISTRIBUTING  
12 MATERIAL.

13 OUR FIRST CONCERN WITH THIS KIND OF A SHALL  
14 SHARE AGREEMENT AND WITHOUT ANY KIND OF EXCEPTIONS TO  
15 WHAT IF IT'S ALREADY COMMERCIALY AVAILABLE IS IT TAKES  
16 AWAY THE INCENTIVE TO LICENSE THIS. LET'S TAKE THE  
17 CASE OF A HYBRIDOMA THAT HAS BEEN DEVELOPED FOR AN  
18 ANTIBODY. IF CIRM OR ANY RESEARCHER IS FORCED TO  
19 DISTRIBUTE THIS HYBRIDOMA TO EVERYBODY, THERE IS VERY  
20 LITTLE INCENTIVE FOR SOMEONE TO COME IN AND LICENSE  
21 THAT HYBRIDOMA. IT JUST TAKES AN ECONOMIC INCENTIVE,  
22 WHICH I DON'T THINK IS WHAT CIRM HAS INTENDED TO DO,  
23 AND IT TAKES AWAY FROM THE ABILITY TO STANDARDIZE TOOLS  
24 AND REAGENTS.

25 THE SECOND CONCERN IS ACTUALLY TOWARDS WHAT

1     HAPPENS IF THERE ARE REAGENTS OR TOOLS THAT ARE  
2     INVENTED USING MULTIPLE SOURCES OF IP, AND I'LL GIVE  
3     YOU ONE PARTICULAR EXAMPLE HERE.  SOMEBODY BROUGHT UP  
4     THE USE OF CELL LINES BEFORE.  AND ONE COULD CONCEIVE  
5     OF ENGINEERED CELL LINES WHERE YOU WOULD TAKE A CELL, A  
6     HUMAN EMBRYONIC STEM CELL LINE, AND ENGINEER IT TO,  
7     SAY, GLOW GREEN OR RED IF A PARTICULAR PATHWAY IS  
8     ACTIVATED.  THIS IS NOT HYPOTHETICAL.  WE ACTUALLY HAVE  
9     COLLABORATIONS IN PLACE TO DO THIS.  PART OF THIS HAS  
10    CONTRIBUTIONS OF RIP INTO THESE CELL LINES, AND THIS  
11    LANGUAGE VERY CLEARLY STATES THAT IF THE CELL LINE HAS  
12    BEEN DEVELOPED USING CIRM MONEY, SO-AND-SO HAS TO --  
13    THE RESEARCHER HAS TO ACTUALLY PROVIDE THIS WHOEVER  
14    ASKS FOR IT, BUT THAT CLEARLY WOULD VIOLATE OUR IP AND  
15    TAKE AWAY ALL OUR INCENTIVE TO COLLABORATE AGAIN WITH  
16    SUCH THIRD PARTY.

17                 SO, AGAIN, IT SEEMS TO ME THAT IT TAKES --  
18    SOME OF THE LANGUAGE WITHOUT MODIFICATION WOULD TAKE  
19    AWAY THE INCENTIVES THAT CIRM IS VERY MUCH WILLING TO  
20    PROVIDE TO THIS COMMUNITY TO HASTEN THE PACE OF  
21    RESEARCH AND COLLABORATION.

22                 DR. PENHOET:  ANY OTHER COMMENTS FROM THE  
23    PUBLIC?  BACK TO THE BOARD.  OS STEWARD.

24                 DR. STEWARD:  I ACTUALLY JUST REALIZED  
25    SOMETHING.  DOES THIS H(B) IN SECTION I HERE MEAN TO

1 IMPLY ANY REQUEST FROM ANYONE IN THE WORLD, OR ARE WE  
2 LIMITING THIS TO CALIFORNIANS?

3 DR. PENHOET: NO. THE INTENT HERE WAS TO  
4 WITHIN CIRM TERRITORY, WHICH IS THE STATE OF  
5 CALIFORNIA, BECAUSE OF THE LACK OF RECIPROCITY FROM THE  
6 REST OF THE WORLD.

7 DR. STEWARD: RIGHT. THAT'S WHAT I THOUGHT,  
8 BUT THAT ACTUALLY ISN'T STATED IN HERE. IS THAT  
9 SOMETHING THAT NEEDS TO BE ADDED?

10 DR. PENHOET: WE WILL ADD THAT TO CLARIFY  
11 THAT POINT.

12 DR. STEWARD: IF I COULD, THAT ACTUALLY, I  
13 THINK, ELIMINATES THE CONCERN ABOUT LICENSING BECAUSE,  
14 AFTER ALL, YOU WOULD STILL WANT TO LICENSE IF YOU  
15 WANTED TO MAKE IT AVAILABLE TO THE REST OF THE WORLD.  
16 I THINK IT'S NOT -- AS LONG AS THAT'S AN INCENTIVE, I  
17 DON'T THINK THAT REALLY RELATES.

18 DR. PENHOET: WELL, I THINK SOMEWHERE IN HERE  
19 WE HAVE TO SAY AS LONG AS THEY'RE LEGALLY FREE TO DO SO  
20 THE SHARING THAT'S IN PLACE BECAUSE IF THEY HAVE A  
21 LEGAL CONSTRAINT AS A RESULT OF A COLLABORATION WITH A  
22 THIRD PARTY, SO WE WILL HAVE TO ADD THAT AS WELL. IN  
23 FACT, WE COULD ADD IT TO THIS UNLESS LEGALLY  
24 CONSTRAINED OR LEGALLY PRECLUDED BY THIRD-PARTY  
25 AGREEMENTS, GRANTEEES SHALL.

1                   MR. SHESTACK: I HAVE A QUESTION THAT APPLIES  
2 TO THIS, BUT IT WILL APPLY TO EVERYTHING, WHICH IS DO  
3 THESE REGULATIONS SURVIVE THE CIRM IF THE CIRM DOESN'T?

4                   DR. PENHOET: I BELIEVE THE ANSWER IS NO, BUT  
5 JAMES PROBABLY KNOWS THE ANSWER.

6                   MR. SHESTACK: OR IS THERE ANY UNDEFINED  
7 TERM?

8                   MR. HARRISON: THERE ARE PROVISIONS IN THE  
9 GRANTS ADMINISTRATION POLICY, AND ARLENE CAN PROBABLY  
10 SPEAK TO THIS BETTER THAN I CAN, THAT SURVIVE THE  
11 TERMINATION OF THE CIRM.

12                  DR. PENHOET: FOR STATE-FUNDED RESEARCH.

13                  MR. HARRISON: FOR STATE-FUNDED RESEARCH.  
14 WE'LL HAVE TO VERIFY ON A BREAK WHETHER THE IP  
15 PROVISIONS ARE SUBJECT TO THAT RULE.

16                  MR. SHESTACK: COULD YOU WRITE LANGUAGE IN  
17 HERE TO SAY THAT THEY ARE? THIS IS THE OPPORTUNITY TO  
18 SPELL THAT OUT; IS THAT CORRECT?

19                  MR. HARRISON: THAT'S RIGHT.

20                  MR. SHESTACK: SOMETHING TO CONSIDER.

21                  DR. REED: IF I COULD FOLLOW UP ON THIS, ONE  
22 OF THE ISSUES IS A DECADE FROM NOW A LABORATORY THAT IS  
23 DEVELOPING A CERTAIN REAGENT MAY HAVE MOVED ON AND MAY  
24 NO LONGER HAVE CIRM FUNDING, MAY NOT EVEN BE DOING STEM  
25 CELL RESEARCH, AND THERE'S NO TERM ON THIS CONTRACT,

1 WHICH MEANS THAT FROM NOW TILL, I GUESS, THE DAY THEY  
2 DIE THEY'LL BE OBLIGATED TO CONTINUE TO PROVIDE THIS  
3 REAGENT. I THINK SOME TERM WOULD BE REASONABLE.

4 MR. SHESTACK: BY THE SAME TOKEN, THE REAGENT  
5 MAY BE CREATED NOW THAT PROVIDES FOR A PRODUCT. IF  
6 CIRM DOESN'T EXIST, NEVERTHELESS YOU WANT SOME OF THESE  
7 IP REGULATIONS TO EXIST, THE STATE TO GET THE BENEFIT,  
8 MANDATORY CROSS LICENSING, ALL THOSE THINGS AS WELL.

9 DR. PENHOET: I THINK YOU MAKE A GOOD POINT  
10 ABOUT TERM. REASONABLE TERM MIGHT BE FIVE YEARS OR  
11 SOMETHING LIKE THAT. IT COULD BE PUT IN THIS KIND OF  
12 DOCUMENT.

13 DR. BRYANT: I THINK IF WITH THE AT-COST  
14 PROVISION, I THINK THAT ALLOWS SOMEBODY TO MAKE SURE  
15 THIS HAPPENS EVEN AFTER CIRM DISAPPEARS IF THERE'S A  
16 VALUABLE REAGENT THAT SHOULD BE PROVIDED. IF IT MEANS  
17 THAT YOU HAVE TO ARRANGE FOR SOMEBODY ELSE TO MAKE IT,  
18 THEN IF YOU ARE DOING IT AT COST, IT WILL MAKE SURE  
19 THAT THAT REAGENT IS STILL AVAILABLE.

20 MR. SERRANO-SEWELL: CALL THE QUESTION.

21 DR. PENHOET: WE HAVE NOW ADDED UNLESS  
22 LEGALLY PRECLUDED TO THE FIRST SENTENCE. AND IS IT THE  
23 SENSE OF THIS BOARD THEY WOULD LIKE TO ADD A TERM, OR  
24 YOU THINK THIS IS ADEQUATELY COVERED BY THE AT-COST  
25 PREVISION FOR THE STAGE OF THE DEVELOPMENT OF THIS

1 REGULATION?

2 MR. SERRANO-SEWELL: BEFORE I CALL THE  
3 QUESTION, I WANTED TO ACCEPT THE AMENDMENT THAT YOU  
4 MADE.

5 MR. SHEEHY: SECOND IS ALSO ACCEPTING THOSE  
6 AMENDMENTS.

7 CHAIRMAN KLEIN: THE SECOND IS ALSO ACCEPTING  
8 THOSE AMENDMENTS AS DR. PENHOET HAS DESCRIBED THEM.

9 MR. SHEEHY: I WOULD THINK THAT AT COST  
10 CAPTURES THE PROBLEM OF TERM.

11 DR. PENHOET: I'M SORRY. YOU BELIEVE AT COST  
12 WOULD CAPTURE THAT, AT LEAST DEAL WITH IT. SO WE HAVE  
13 A MOTION AND A SECOND FOR THE LANGUAGE THAT'S INDICATED  
14 HERE, DELETION OF THOSE PARTS WHICH ARE OUTLINED IN  
15 GREEN, AND ADDITION OF THOSE PARTS WHICH ARE BOLDED IN  
16 RED. I WILL READ IT.

17 GRANTEES SHALL SHARE BIOMEDICAL MATERIALS  
18 DESCRIBED IN PUBLISHED SCIENTIFIC ARTICLES FOR RESEARCH  
19 PURPOSES IN CALIFORNIA WITHIN 60 DAYS OF RECEIPT OF A  
20 REQUEST AND WITHOUT BIAS AS TO THE AFFILIATION OF THE  
21 REQUESTER UNLESS LEGALLY PRECLUDED. UNDER SPECIAL  
22 CIRCUMSTANCES, EXCEPTIONS TO THE ABOVE ARE POSSIBLE  
23 WITH THE APPROVAL BY CIRM. AND HERE WE HAVE THE  
24 COMMITMENT TO GO BACK DURING THE 270 DAYS AND DEFINE  
25 THOSE CIRCUMSTANCES WELL. THAT'S THE END OF THAT

1 SENTENCE. ALTERNATIVELY AUTHORS MAY PROVIDE REQUESTERS  
2 INFORMATION ON HOW TO RECONSTRUCT OR OBTAIN THE  
3 MATERIALS TO BE SHARED WITHOUT COST, OR AT COST.  
4 THAT'S AT THEIR DISCRETION.

5 THAT'S IT. THEN THE LAST SENTENCE IS NOW  
6 DELETED. WE HAVE A MOTION AND A SECOND. CAN I ASK FOR  
7 YOUR VOTE.

8 MS. SAMUELSON: QUESTION. MY QUESTION GOES  
9 MORE BROADLY, I THINK, TO THE WHOLE DOCUMENT. I'M  
10 COMFORTABLE RELYING ON THE HARD WORK OF THE TASK FORCE  
11 IN THIS DISCUSSION TO FINALIZE THIS DOCUMENT, BUT I  
12 THINK WE SHOULD INVITE WITHIN OUR OWN PROCESS AND NOT  
13 JUST LEAVE TO THE APA PROCESS A COMMENT PERIOD FOR  
14 OTHERS IN THE FIELD IN CALIFORNIA AND BEYOND WHO MIGHT  
15 HAVE COMMENTS AND CONCERNS THAT MIGHT IMPROVE UPON IT.  
16 SOUNDS LIKE IT IS BREAKING SO MUCH NEW GROUND, THAT  
17 MIGHT BE A USEFUL ADDITION.

18 DR. PENHOET: I BELIEVE WE'VE HAD FOUR OPEN  
19 MEETINGS OF OUR TASK FORCE. WE HAD LOTS OF INPUT FROM  
20 ALL THE SECTORS THAT I'VE HEARD REPRESENTED HERE TODAY,  
21 AND WE'VE HAD AMPLE TIME IN EVERY ONE OF THOSE MEETINGS  
22 FOR FULL DISCUSSION OF THEIR CONCERNS. WE SHOULD  
23 ALWAYS BE OPEN TO FURTHER INPUT GOING FORWARD, BUT I  
24 BELIEVE THAT WE'VE BEEN VERY RESPONSIVE. WE CAN'T  
25 SOLVE EVERYONE'S PROBLEMS BECAUSE OBVIOUSLY PEOPLE HAVE



1 DIFFERENT POINTS OF VIEW ABOUT THESE. SO OUR TASK  
2 FORCE HAS WORKED HARD TO FIND A WORKABLE AND SENSIBLE  
3 MIDDLE GROUND, AND WE'VE HAD LOTS OF INPUT FROM LOTS OF  
4 PEOPLE, BUT WE WILL CONTINUE TO DO THAT.

5 AS JAMES SAID, THERE WILL BE FURTHER PUBLIC  
6 HEARING IN THE 270-DAY PERIOD, AND IN EVERY ONE OF OUR  
7 MEETINGS, WE'RE, I'M SURE, PERFECTLY HAPPY TO CONTINUE  
8 TO DISCUSS THESE ISSUES.

9 DR. REED: I THINK I'M COMFORTABLE WITH  
10 WORKING THIS PROCESS TO APPROVE A DOCUMENT TODAY THAT  
11 WE FEEL IS A REASONABLE APPROACH AT THIS. I WAS  
12 INVOLVED IN AT LEAST PARTS OF THIS, AND I KNOW HOW MUCH  
13 WORK WENT INTO THIS. I THINK THE MAIN THING, THOUGH,  
14 IS FOR US TO SIMPLY RESOLVE OURSELVES THAT, SAY, TWO  
15 YEARS FROM NOW, WE'RE GOING TO COME BACK AND LOOK AT  
16 THIS AGAIN AND CAN ASK FOR INPUT OF IS THIS WORKING OR  
17 IS IT NOT WORKING WITH THE COMMITMENT THAT IF WE NEED  
18 TO REVISE THINGS, WE'LL AMEND AT THAT TIME.

19 DR. PENHOET: SENSIBLE PROPOSAL. OKAY. CALL  
20 THE QUESTION. ALL IN FAVOR OF ADOPTING (A), WHICH IS  
21 HERE, WHICH WE MADE NO CHANGES; AND (B) WITH THE  
22 PROPOSED CHANGES THAT CAME OUT OF THIS DISCUSSION HERE  
23 THIS MORNING. ALL IN FAVOR. OPPOSED? THANK YOU.

24 WE'LL NOW MOVE TO SECTION C. WE JUST HAVE  
25 ONE CHANGE HERE, WHICH IS DEVELOP TO MADE IN THE

1 PERFORMANCE OF CIRM-FUNDED RESEARCH. REMIND YOU OUR  
2 GRANTEES WILL OWN THE TECHNOLOGY. AND AS PART OF THEIR  
3 OWNERSHIP, THEY TAKE ON THE RESPONSIBILITY OF  
4 DILIGENTLY PURSUING PATENTS WHERE THEY BELIEVE THAT  
5 SUCH PATENTS WILL BE USEFUL. SO THIS IS AN APPLICATION  
6 REQUIREMENT.

7 THE NEXT ONE SPEAKS TO THE ISSUE OF  
8 LICENSING. AND BECAUSE OF ITS IMPORTANCE, LET ME READ  
9 THIS PART. GRANTEE ORGANIZATION SHALL ASSUME  
10 RESPONSIBILITY FOR LICENSING ACTIVITIES, INCLUDING  
11 IDENTIFICATION OF LICENSEES, NEGOTIATION OF AGREEMENTS,  
12 AND DOCUMENTATION OF DEVELOPMENTAL PROGRESS FOR  
13 LICENSES RELATED TO CIRM-FUNDED PATENTED INVENTIONS.  
14 GRANTEE ORGANIZATIONS ARE REQUIRED TO SUBMIT A  
15 LICENSING ACTIVITIES REPORT RELEVANT TO CIRM-FUNDED  
16 PATENTED INVENTIONS ON AN ANNUAL BASIS. WE EXPECT,  
17 AGAIN, THIS WAS TO CONFORM TO CURRENT REPORTING  
18 REQUIREMENTS. WE HAVE AN ANNUAL REPORT, WHICH IS GOING  
19 TO BE REQUIRED FOR MANY OTHER ACTIVITIES ON THEIR PART,  
20 SO THIS WOULD SIMPLY BE PART OF THE ANNUAL REPORT OF  
21 GRANTEES TO CIRM.

22 SECOND PART, GRANTEE ORGANIZATIONS SHALL  
23 NEGOTIATE NONEXCLUSIVE LICENSES OF CIRM-FUNDED  
24 INVENTIONS WHENEVER POSSIBLE. NEVERTHELESS, GRANTEE  
25 ORGANIZATIONS MAY NEGOTIATE AND AWARD EXCLUSIVE

1 LICENSES FOR CIRM-FUNDED INVENTIONS RELEVANT TO  
2 THERAPIES AND DIAGNOSTICS IF SUCH LICENSES ARE  
3 NECESSARY TO PROVIDE ECONOMIC INCENTIVES REQUIRED TO  
4 ENABLE COMMERCIAL DEVELOPMENT AND AVAILABILITY OF THE  
5 INVENTIONS. IN DUE DILIGENCE RELATED TO SUCH LICENSES,  
6 GRANTEE ORGANIZATIONS SHALL DOCUMENT DEVELOPMENT OF  
7 COMMERCIALIZATION CAPABILITIES OF THE INTENDED LICENSEE  
8 AND INCLUDE TERMS IN THE LICENSE AGREEMENT ADDRESSING  
9 ALL RELEVANT THERAPEUTIC AND DIAGNOSTIC USES FOR WHICH  
10 THE INVENTION IS APPLICABLE.

11 DURING OUR PROCESS OF DISCUSSING THIS NO. 2  
12 HERE IN OUR COMMITTEE AND SUBSEQUENTLY, WE HAVE GOTTEN  
13 TWO PIECES OF FEEDBACK THAT I WOULD LIKE TO PUT BEFORE  
14 YOU FOR YOUR CONSIDERATION.

15 ONE IS THAT WE NOT LIMIT THE POSSIBILITY OF  
16 EXCLUSIVE LICENSEES TO THERAPIES AND INVENTIONS, BUT,  
17 IN FACT, TO INCLUDE ALL POTENTIAL USES OF THESE. THIS,  
18 WE THINK, WOULD PROVIDE INCENTIVES FOR THE PRIVATE  
19 SECTOR TO DEVELOP THESE UNDER CERTAIN CIRCUMSTANCES AND  
20 ESSENTIALLY GIVE THE RESEARCH ORGANIZATIONS WHO, IN A  
21 SENSE, PROVIDE REAGENTS, ETC., FOR THIS ENTIRE FIELD  
22 THE OPPORTUNITY TO DO THAT UNDER THESE CIRCUMSTANCES.

23 WHAT I SAID BEFORE WHEN I MENTIONED THIS  
24 ISSUE IS MY OWN PERSONAL VIEW, THAT SHOULD BE COUPLED  
25 WITH AN APPROVAL BY CIRM SO IT DOES NOT -- A LICENSE

1 FOR A NONTHERAPEUTIC OR DIAGNOSTIC USE MADE EXCLUSIVELY  
2 SHOULD BE SUBJECT TO APPROVAL BY CIRM BECAUSE CIRM IS  
3 RESPONSIBLE FOR OVERSIGHT OF THE RESEARCH ACTIVITIES.  
4 SO THAT'S ONE POSSIBILITY THAT YOU COULD ADD TO THIS  
5 PARAGRAPH.

6 AND THE SECOND ONE IS THE NEED FOR ANY  
7 SUBSTANTIAL FOLLOW-UP IN TERMS OF DILIGENCE, ETC., FOR  
8 NONEXCLUSIVE LICENSES. TO SOME DEGREE THE MARKETPLACE  
9 SHOULD TAKE CARE OF THIS. IF YOU HAVE NUMEROUS  
10 LICENSEES, PRESUMABLY IF ONE LICENSEE IS NOT PURSUING  
11 AN AVENUE, ANOTHER LICENSEE IS FREE TO DO THAT. SO THE  
12 SECOND PROPOSED CHANGE TO THIS PARAGRAPH WOULD BE THAT  
13 ALL THE DEVELOPMENT AND OTHER ASPECTS CALLED FOR IN THE  
14 LAST SENTENCE OF THIS WOULD BE ONLY FOR EXCLUSIVE  
15 LICENSEES, NOT FOR NONEXCLUSIVE LICENSEES. IT'S QUITE  
16 A BURDEN TO COLLECT ALL THIS INFORMATION, FRANKLY. AND  
17 NONEXCLUSIVE LICENSEES PER SE PROVIDE AN OPPORTUNITY  
18 FOR ADDRESSING THIS, BUT EACH LICENSEE IS FREE TO DO  
19 WHAT THEY WANT.

20 SO THIS PART HERE, I THINK, WE WOULD LIKE TO  
21 DISCUSS SEPARATELY. LET ME JUST ASK ARE THERE ANY  
22 COMMENTS ON PART C BEFORE WE MOVE ON TO THE DISCUSSION  
23 OF PART D?

24 IF NOT, THEN LET'S DISCUSS PART D. SO THIS  
25 IS THE LANGUAGE THAT WE CAME UP WITH AS A RESULT OF OUR

1 WORK IN THE SUBCOMMITTEE. THE TWO POTENTIAL  
2 MODIFICATIONS I JUST MENTIONED TO YOU HAVE BEEN BROUGHT  
3 TO US BY SEVERAL DIFFERENT GROUPS, AND SO I THROW THAT  
4 OUT FOR YOUR DISCUSSION.

5 THE FIRST ONE BEING SHOULD WE LIMIT EXCLUSIVE  
6 LICENSEES ONLY TO THERAPIES AND DIAGNOSTICS, OR SHOULD  
7 WE PROVIDE THE OPPORTUNITY FOR EXCLUSIVE LICENSES FOR  
8 ALL USES WITH THE PROVISIO THAT RESEARCH TOOLS OR THINGS  
9 THAT ARE PRIMARILY USED IN A RESEARCH SETTING WOULD BE  
10 SUBJECT TO APPROVAL BY CIRM. SO THAT'S THE FIRST THING  
11 I'D LIKE DISCUSSION BY THE GROUP HERE.

12 MR. SHEEHY: DO WE HAVE THE SPECIFIC LANGUAGE  
13 YOU ARE TALKING ABOUT?

14 DR. PENHOET: I'M SORRY?

15 MR. SHEEHY: I KNOW WHERE YOU ARE, I MEAN  
16 SPECIFICALLY WHAT YOU'RE PROPOSING THAT IT SAY.

17 DR. PENHOET: I'M NOT MAKING A PROPOSAL. I'M  
18 SIMPLY STATING THAT IT WAS PROPOSED TO US THAT WE  
19 CONSIDER HERE TODAY REMOVING THE RESTRICTION ON  
20 EXCLUSIVE LICENSEES, WHICH IS ONLY FOR THERAPEUTICS AND  
21 DIAGNOSTICS AS INDICATED UNDER NO. 2, TO MAKE IT ALL  
22 TECHNOLOGY, ALL PATENTED INVENTIONS SO THAT EXCLUSIVE  
23 LICENSES ARE POSSIBLE FOR ANY USE OF TECHNOLOGY.

24 MR. SHEEHY: I UNDERSTAND THE CONCEPT. I'M  
25 TRYING TO UNDERSTAND THE LANGUAGE. SO ARE YOU JUST

1 TALKING ABOUT STRIKING RELEVANT TO THERAPIES AND  
2 DIAGNOSTICS?

3 DR. PENHOET: THAT'S CORRECT. BUT ADDING  
4 THAT WHEN SUCH LICENSES ARE GRANTED FOR RESEARCH TOOLS,  
5 THAT THINGS THAT ARE USED PRIMARILY FOR RESEARCH, NOT  
6 THERAPIES AND DIAGNOSTICS, THAT THEY WOULD BE SUBJECT  
7 TO REVIEW BY CIRM. THAT'S MY OWN PERSONAL ADDITION TO  
8 THIS.

9 MR. SHEEHY: THIS IS THE SECOND PLACE WE'VE  
10 PUT IN REVIEW BY CIRM. SHOULD THEY NOT BE REPORTING TO  
11 THE ICOC FOR POTENTIAL ACTION? I DON'T THINK WE NEED  
12 TO MAKE IT DEPENDENT ON ACTION BY THE ICOC, BUT IT  
13 SHOULD BE REPORTED WITH THE OPTION FOR ACTION AT THE  
14 NEXT ICOC MEETING.

15 DR. PENHOET: WELL, IF I MIGHT ASK FOR A  
16 SENTIMENT OF THE GROUP ON THIS ISSUE. THERE'S BEEN A  
17 PROPOSAL THAT WE DON'T RESTRICT EXCLUSIVE LICENSES TO  
18 THERAPIES AND DIAGNOSTICS, BUT MAKE IT BROAD FOR ANY  
19 USE, BUT IMPOSE A HIGHER HURDLE FOR INVENTIONS THAT ARE  
20 NOT THERAPIES OR DIAGNOSTICS, THE HURDLE BEING CIRM  
21 WOULD HAVE TO APPROVE SUCH A LICENSE. THIS IS NOT A  
22 VOTE. THIS IS YOUR SENTIMENT AS A GROUP. HOW MANY OF  
23 YOU ARE GENERALLY IN FAVOR OF MOVING IN THAT DIRECTION?  
24 HOW MANY OF YOU ARE AGAINST MOVING IN THAT DIRECTION?  
25 WE HAVE A LOT OF PEOPLE WITH NO OPINION ON THIS ISSUE,

1 BUT IT'S TWO TO ZERO, I GUESS.

2 DR. JENNINGS: I'D LIKE TO SPEAK IN SUPPORT  
3 OF IT BECAUSE OF THE NOT UNTYPICAL CASE OF A NEW  
4 RESEARCH TOOL OR DEVICE BEING DEVELOPED AND THE ONLY  
5 PERSON THAT REALLY BELIEVES IT'S GOING TO WORK IS THE  
6 INVENTOR AND HE HAS A LITTLE START-UP COMPANY. YOU  
7 OFFER THE TECHNOLOGY OUT TO THE BIG COMPANIES, THEY  
8 DON'T WANT IT, AND THE ONLY WAY IT'S GOING TO GET INTO  
9 THE MARKET IS IF THESE PEOPLE BELIEVE IT WILL WORK,  
10 START A LITTLE START-UP COMPANY, AND THE VENTURE  
11 CAPITALIST WILL REQUIRE EXCLUSIVE LICENSES. THERE'S A  
12 LONG TIME TO DEVELOPMENT HERE. IT JUST MAKES VERY GOOD  
13 SENSE FOR US AT CIRM TO HAVE THE POSSIBILITY OF THESE  
14 DEVICES AND TOOLS AND INVENTIONS BEING DEVELOPED IN A  
15 PRACTICAL SENSE, AND IT REALLY WON'T HAPPEN IF IN A  
16 NONEXCLUSIVE ENVIRONMENT.

17 DR. PENHOET: WOULD YOU OBJECT TO A HIGHER  
18 BAR; THAT IS, REVIEW BY CIRM UNDER THOSE CIRCUMSTANCES?

19 DR. JENNINGS: EXCUSE ME?

20 DR. PENHOET: WOULD YOU OBJECT TO A HIGHER  
21 THRESHOLD ESSENTIALLY FOR APPROVAL; THAT IS, CIRM WOULD  
22 REVIEW THOSE KINDS OF THINGS?

23 DR. JENNINGS: NO, NOT AT ALL.

24 DR. POMEROY: I THINK ONE OF THE REASONS THAT  
25 SOME OF US MAY NOT HAVE ANSWERED YOUR QUESTION WAS

1 BECAUSE IT'S NOT CLEAR, AT LEAST TO ME, WHAT THE ROLE  
2 OF CIRM OR THE ICOC SHOULD BE IN DETERMINING EXCLUSIVE  
3 LICENSES FOR ANY OF THESE THINGS, NOT JUST RESEARCH  
4 TOOLS. YOUR PROPOSAL WAS JUST ABOUT CIRM REVIEW FOR  
5 RESEARCH TOOLS, IF I HEARD IT APPROPRIATELY.

6 DR. PENHOET: THAT'S A PERSONAL OPINION AS  
7 ONE OF 29 MEMBERS. I DON'T WANT TO STATE THAT AS A  
8 CONCLUSION OF OUR COMMITTEE.

9 DR. POMEROY: THAT'S DIFFICULT TO ANSWER, SO  
10 I THINK OUR CHARGE IS TO TRY TO GIVE SOME GUIDANCE OF  
11 WHAT THE PROCESS SHOULD BE FOR GRANTING ANY EXCLUSIVE  
12 LICENSES FOR ANY OF THESE CATEGORIES, AND HOW MUCH  
13 SHOULD BE THE GRANTEE'S RESPONSIBILITY AND HOW MANY  
14 SHOULD REQUIRE ICOC OR CIRM OVERSIGHT OR REVIEW OR  
15 APPROVAL OR ENDORSEMENT OR SOME WORD LIKE THAT.

16 DR. PENHOET: WELL, AT THE MOMENT AT LEAST  
17 EXCLUSIVE LICENSEES HAVE TWO BURDENS. THEY HAVE TO  
18 PROVIDE A DETAILED PLAN WITH MILESTONE AND OTHER  
19 MEASURES OF THEIR SUCCESSFUL COMMERCIALIZATION OF THE  
20 TECHNOLOGY THAT THEY HAVE INVENTED, WHICH IS ONE. AND  
21 SECOND OF ALL, THEY HAVE TO AGREE TO LIVE BY THE  
22 SHARING RULES THAT WILL BE PART OF THE COMMUNITY FOR  
23 THEIR ACTIVITIES WITHIN THE STATE OF CALIFORNIA. AND  
24 UNDER THERAPIES AND DIAGNOSTICS, THERE'S A CLEAR  
25 GENERAL PRECEDENT FOR THIS, BUT IT'S ALSO TRUE, AS



1 DR. JENNINGS POINTS OUT, THAT COMMERCIALIZATION OF  
2 TOOLS IS AN IMPORTANT PART.

3 YOU KNOW, THE OTHER SIDE OF THE ARGUMENT IS  
4 THAT THIS IS ONE OF THE ISSUES THAT THE NATIONAL GROUPS  
5 HAVE TRIED TO ADDRESS, AND I THINK THERE'S PROBABLY,  
6 AGAIN, SPEAKING FOR MYSELF, NO PERFECT ANSWER TO THIS  
7 ISSUE.

8 DR. LOVE: I WAS JUST GOING TO MAKE THE POINT  
9 THAT I'M NOT SURE IF CIRM OR THE ICOC KNOWS MORE --  
10 KNOWS AS MUCH ABOUT THESE DECISIONS OF EXCLUSIVE AND  
11 NONEXCLUSIVITY AS THE GROUP WE'D BE TRYING TO TELL WHAT  
12 TO DO. AND SO I WOULD ACTUALLY SUBMIT THAT THIS IS AN  
13 AREA WHERE WE PROBABLY DON'T WANT TO GO, BUT RATHER  
14 DELEGATE THAT DECISION TO GROUPS THAT HAVE BEEN DOING  
15 IT WELL FOR YEARS.

16 DR. PENHOET: WELL, WE HAVE THREE  
17 ALTERNATIVES. LEAVE THE LANGUAGE AS IT IS, MODIFY THE  
18 LANGUAGE TO REMOVE THE RESTRICTION OF EXCLUSIVE  
19 LICENSEES TO SOLELY THERAPEUTICS AND DIAGNOSTICS; THAT  
20 IS, WOULD INCLUDE ALL USES; AND THE THIRD ALTERNATIVE  
21 WOULD BE TO ADD LANGUAGE THAT SAYS FOR USES OTHER THAN  
22 THERAPEUTICS AND DIAGNOSTICS, LIKE GRANTEES WOULD HAVE  
23 TO SEEK APPROVAL BY CIRM FOR THEIR EXCLUSIVE LICENSES  
24 OF OTHER USES OTHER THAN THERAPIES AND DIAGNOSTICS.  
25 THOSE ARE THE THREE ALTERNATIVES WE HAVE IN FRONT OF

1 US.

2 LET ME ASK THE QUESTION A DIFFERENT WAY THEN.  
3 THE TWO SORT OF BINARY CHOICES, DO WE VOTE FOR REMOVING  
4 THE RESTRICTION TO THERAPIES AND DIAGNOSTICS UNMODIFIED  
5 BY ANYTHING ELSE, AND MAYBE WE ADDRESS THAT ONE FIRST.  
6 I KNOW THERE ARE PEOPLE IN THIS AUDIENCE WHO HAVE A  
7 POINT OF VIEW ABOUT THAT, SO AT THIS POINT WITH YOUR  
8 AGREEMENT, I'D LIKE TO ASK FOR PUBLIC COMMENT.

9 DR. REED: I WAS GOING TO MAKE A MOTION THAT  
10 WE ADOPT THE LANGUAGE THAT'S PRESENTED ON THE SCREEN AT  
11 THIS MOMENT.

12 MR. SHEEHY: I SECOND.

13 DR. PENHOET: WHAT'S ON THE SCREEN NOW  
14 DELETES THE WORDS "RELEVANT TO THERAPIES AND  
15 DIAGNOSTICS."

16 MR. SIMPSON: JOHN SIMPSON FROM THE  
17 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. IT SEEMS  
18 TO ME THAT ONE OF THE GROUNDBREAKING AREAS OF YOUR IP  
19 POLICY WAS THE NOTION OF MAXIMUM SHARING. THERE HAVE  
20 BEEN A LOT OF COMPLAINTS ABOUT SO-CALLED UPSTREAM  
21 PATENT THICKETS THAT REALLY GET IN THE WAY OF RESEARCH  
22 AND SLOW THINGS DOWN. WHAT I'M AFRAID YOU'RE STARTING  
23 TO DO HERE IS SET A POLICY THAT SAYS NONEXCLUSIVE ARE  
24 PREFERABLE, BUT THEN YOU'RE OPENING IT UP SO THAT  
25 EVERYONE WILL SAY, YEP, WE'LL GO EXCLUSIVELY.

1                   SO IT WOULD SEEM TO ME AT THE VERY LEAST  
2   YOU'VE GOT TO DO WHAT THE CHAIRMAN OF THE IP TASK FORCE  
3   SUGGESTS IS THAT THERE HAS TO BE A HIGH LEVEL OF  
4   THRESHOLD TO BE ABLE TO GO OVER IF YOU ARE GOING TO GO  
5   TO A NONEXCLUSIVE LICENSE. AND THEN I WOULD THINK THAT  
6   IT WOULD HAVE TO COME BACK TO CIRM FOR APPROVAL. I  
7   WOULD SUGGEST THAT THAT SHOULD BE WITH ALL LICENSES,  
8   NOT JUST THE RESEARCH TOOLS, BUT AT A MINIMUM IT'S GOT  
9   TO BE WITH THE RESEARCH TOOLS.

10                MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
11   CALIFORNIA. AND I WOULD ARGUE TO KEEP THE LANGUAGE  
12   EXACTLY AS IS PROPOSED RIGHT HERE WITHOUT THE CIRM  
13   OVERSIGHT, WHICH ADDS AN ADDITIONAL BURDEN TO THOSE  
14   FOLKS WHO ARE SO DESPERATELY TRYING TO GET LICENSES.  
15   YOU HAVE A NUMBER OF SAFEGUARDS ALREADY BUILT IN.  
16   YOU'VE PRESERVED RESEARCH USE, YOU'VE REQUIRED DILIGENT  
17   DEVELOPMENT OF THE LICENSEE, AND YOU'VE RESERVED  
18   MARCH-IN RIGHTS, WHICH IS PROBABLY SUFFICIENT TO  
19   SAFEGUARD THE FUNDAMENTAL PRINCIPLES THAT ARE IMPORTANT  
20   TO CIRM.

21                MR. GOSWAMI: I THINK WE WOULD OBVIOUSLY  
22   SUPPORT THE OPENING UP OF EXCLUSIVE LICENSING. I THINK  
23   ONE OF THINGS, AGAIN, WE'VE BEEN INVOLVED IN ABOUT 40  
24   LICENSES A YEAR FROM ACADEMIC INSTITUTIONS. I THINK  
25   IT'S FAIR TO SAY THAT THE FREE MARKET, AT LEAST IN THE

1 UNITED STATES, KNOWS HOW TO HANDLE WHEN TO GIVE AN  
2 EXCLUSIVE AND A NONEXCLUSIVE LICENSE. I THINK THERE  
3 HAVE BEEN A LOT OF COMPLAINTS ON TECHNOLOGIES NOT  
4 GETTING TO THE MARKET BECAUSE OF EXCLUSIVE LICENSE; BUT  
5 WHEN YOU ACTUALLY LOOK AT IT, IT'S NOT BECAUSE OF  
6 EXCLUSIVE OR NONEXCLUSIVE LICENSING. IT'S BECAUSE OF  
7 THE IP STATE THAT HAPPENS TO EXIST AND THE  
8 COMPLICATIONS THAT HAPPEN TO EXIST ON THAT.

9 SO I WOULD SUPPORT REMOVING THE RESTRICTION  
10 ON JUST EXCLUSIVE LICENSING TO THAT. I'M ACTUALLY OKAY  
11 WITH CIRM OVERSIGHT INTO IT. I THINK I AGREE WITH THE  
12 UC PERSON WHO SAID THAT IT DOES ADD AN ADDITIONAL  
13 BURDEN, BUT THAT'S YOUR PREROGATIVE TO ADMINISTER THAT.

14 CHAIRMAN KLEIN: DR. PENHOET, EVEN THOUGH  
15 MEMBERS OF THE AUDIENCE SUCH AS THE LAST MEMBER  
16 IDENTIFIED HIMSELF PREVIOUSLY, IT WOULD HELP THE  
17 STENOGRAPHER AND THE TRANSCRIPT IF EACH TIME THEY  
18 SPEAK, UNLESS THEY OBJECT TO IDENTIFYING THEMSELVES, IF  
19 THEY COULD REIDENTIFY THEMSELVES FOR THE BENEFIT OF THE  
20 THOSE PEOPLE NOT PRESENT.

21 MR. GOSWAMI: ABSOLUTELY. JOYDEEP GOSWAMI  
22 FROM INVITROGEN.

23 MS. SAMUELSON: WAS THIS DRAFT SUBMITTED TO  
24 ANY PROFESSIONAL INDUSTRY SOCIETIES OR ACADEMIC  
25 ORGANIZATIONS FOR COMMENT?

1 DR. PENHOET: YES. WE RECEIVED COMMENT FROM  
2 MOST OF THEM. WE'VE GIVEN THEM DRAFTS ALL ALONG.

3 MS. SAMUELSON: ON YOUR DRAFT, ON THE DRAFT,  
4 ON THIS DRAFT?

5 DR. PENHOET: NOT AS WE'RE REMODIFYING. AS  
6 YOU SAW IT, AND WE PROVIDED COPIES OF EVERY PIECE OF  
7 CORRESPONDENCE WE'VE GOTTEN FROM ANYONE ON THIS ISSUE  
8 WHICH ARE OUT ON THE TABLE. SO EVERYTHING WE'VE DONE  
9 IS FULLY TRANSPARENT AT THIS POINT IN TIME, AND WE HAVE  
10 GOTTEN COMMENTS FROM THE INDUSTRY AND INDUSTRY  
11 ORGANIZATIONS. AND THEIR RECOMMENDATION WAS THAT WE  
12 ADOPT THE LANGUAGE WHICH IS CURRENTLY ON THIS SLIDE.  
13 NOT JUST INDUSTRY, UNIVERSITIES AS WELL.

14 THIS DOCUMENT HAS BEEN POSTED IN ITS CURRENT  
15 FORM FOR A WEEK, BUT WE ALSO HAD THE VERSIONS THAT LED  
16 UP TO THIS IN PUBLIC MEETINGS AND WERE DISTRIBUTED.

17 MS. KU: KATHY KU FROM STANFORD UNIVERSITY.  
18 I ALSO WANT TO ENDORSE THE PROPOSED CHANGES WHERE WE  
19 REMOVED THE LIMITATION ON DIAGNOSTIC AND THERAPEUTIC.  
20 WE HAVE HAD A LOT OF EXPERIENCE LICENSING WHAT WE CALL  
21 RESEARCH TOOLS, BUT THEY END UP TO BE EQUIPMENT OR  
22 INSTRUMENTATION. FOR THOSE INVOLVED IN THE RESEARCH  
23 SELF-ELECTROPHORESIS WAS AN EXCLUSIVE LICENSE FOR  
24 OLIGONUCLEOTIDE SYNTHESIZERS, WHICH BROUGHT DOWN THE  
25 PRICE OF OLIGOS DRAMATICALLY, WAS LICENSED EXCLUSIVELY

1 MAINLY BECAUSE NOBODY ELSE WAS INTERESTED IN THIS. AND  
2 THESE STILL ARE RESEARCH TOOLS.

3 DR. PENHOET: ANY OTHER COMMENTS? THANK YOU.  
4 THANKS TO KATHY KU AND WENDY FROM UC. THEY'VE BEEN  
5 VERY IMPORTANT CONTRIBUTORS TO OUR TASK FORCE.

6 DR. PRIETO: QUESTION. IF WE APPROVE THIS  
7 MOTION, WILL YOU ENTERTAIN A SEPARATE MOTION TO ADD THE  
8 OVERSIGHT LANGUAGE THAT YOU HAD SUGGESTED EARLIER?

9 DR. PENHOET: YES. MOTION ON THE TABLE IS TO  
10 APPROVE THIS SUBJECT TO -- WELL, FURTHER MODIFICATION.  
11 WE HAVE ANOTHER ISSUE FURTHER DOWN, BUT SUBJECT TO THE  
12 SECOND PIECE, SO IF WE COULD PARSE THIS VOTE, PLEASE.

13 ANY OTHER COMMENT? ALL IN FAVOR OF THE  
14 LANGUAGE AS INDICATED HERE WITH THE DELETION OF THE  
15 GREEN MATERIAL. ALL IN FAVOR. OPPOSED?

16 OKAY. YOU WANT TO MAKE A SECOND MOTION?

17 DR. PRIETO: I WOULD MOVE THAT WE ADD  
18 LANGUAGE ALLOWING EXCLUSIVE LICENSES FOR RESEARCH TOOLS  
19 SUBJECT TO CIRM APPROVAL.

20 DR. PENHOET: IS THERE A SECOND? I GUESS THE  
21 MOTION DIES FOR LACK OF A SECOND.

22 WE CAN MOVE ON THEN TO THE NEXT ISSUE IN THIS  
23 PARAGRAPH IS FOR NONEXCLUSIVE LICENSES. IS THE COST OF  
24 COMPLYING WITH OUR DUE DILIGENCE REQUIREMENTS, ETC., A  
25 BURDEN WHICH IS REALLY TRULY UNNECESSARY BECAUSE, BY

1     DEFINITION, A NONEXCLUSIVE LICENSE MEANS THERE ARE  
2     MULTIPLE PLAYERS IN THE MARKETPLACE?  SO WE'VE HAD  
3     SEVERAL PEOPLE ASK US TO REMOVE THE REQUIREMENT OF DUE  
4     DILIGENCE, ETC., DOCUMENTING THEIR DEVELOPMENT AND  
5     COMMERCIALIZATION CAPABILITIES.  OBVIOUSLY IN EVERY  
6     LICENSE, I GUESS, THAT WOULD HAPPEN, BUT THAT FOR  
7     NONEXCLUSIVE LICENSE -- THIS WOULD JUST BE APPLIED TO  
8     EXCLUSIVE LICENSES, NOT NONEXCLUSIVE LICENSES.

9             A ONE-WORD CHANGE WOULD TAKE CARE OF THAT.  
10    THE WORD IS WE'LL PUT IN EXCLUSIVE LICENSES, THEN SAY  
11    IN -- WHERE DOES THE WORD GO, MARY? -- TO SUCH  
12    LICENSES, AND SHOULD SAY TO EXCLUSIVE LICENSES RATHER  
13    THAN SUCH LICENSES.  AND SUCH WILL BE REMOVED.  OKAY.  
14    THAT'S THE SECOND PROPOSAL.

15            IS THERE A MOTION IN FAVOR OF THIS CHANGE?

16            DR. LOVE:  SO MOVED.

17            DR. PENHOET:  SO MOVED TED LOVE.  IS THERE A  
18    SECOND?

19            MR. SERRANO-SEWELL:  SECOND.

20            DR. PENHOET:  ALL IN FAVOR.  OPPOSED?  OKAY.  
21    WE CAN MOVE ON.

22            SECTION D, PART 3, SPEAKS TO THE PLAN THAT IF  
23    THERE'S AN EXCLUSIVE ARRANGEMENT, THAT THE GRANTEE  
24    ORGANIZATION SHOULD INCLUDE TERMS FOR DEVELOPMENT PLANS  
25    TO BRING IT TO PRACTICAL APPLICATION, INCLUDE

1 DEVELOPMENT MILESTONES AND BENCHMARKS, ETC. THIS IS  
2 FAIRLY COMMON IN ANY EXCLUSIVE LICENSE.

3 NO. 4, GRANT EXCLUSIVE LICENSES INVOLVING  
4 CIRM-FUNDED PATENTED INVENTIONS RELEVANT TO THERAPIES  
5 AND DIAGNOSTICS TO ORGANIZATIONS WITH PLANS TO PROVIDE  
6 ACCESS TO RESULTANT THERAPIES AND DIAGNOSTICS FOR  
7 UNINSURED PATIENTS. IN ADDITION, SUCH LICENSEES WILL  
8 AGREE TO PROVIDE TO PATIENTS WHOSE THERAPIES WILL BE  
9 PURCHASED -- YOU'RE TESTING THE LIMITS OF MY EYESIGHT  
10 AT THIS POINT -- WILL BE PURCHASED IN CALIFORNIA BY  
11 PUBLIC FUNDS FOR THERAPIES, AND AGAIN DIAGNOSTICS, AT A  
12 COST NOT TO EXCEED, AND THE NEW LANGUAGE WE'RE PUTTING  
13 IN IS FEDERAL MEDICAID PRICE IN EXCHANGE FOR LOWEST  
14 AVAILABLE COMMERCIAL U.S. PRICE.

15 THE PRACTICAL REALITY OF THE UNITED STATES  
16 HEALTHCARE MARKET TODAY IS THE FEDERAL GOVERNMENT IS  
17 THE LOW-COST PURCHASER, AND THEY DO HAVE SO-CALLED  
18 FAVORED NATION CLAUSES IN THEIR OWN PURCHASING  
19 PROGRAMS. SO ALMOST BY DEFINITION THEY HAVE THE LOWEST  
20 AVAILABLE PRICE IN THE U.S. ASSOCIATED WITH MEDICAID.  
21 THIS CHANGE WAS RECOMMENDED TO US BY TWO MEMBERS OF THE  
22 LEGISLATURE, BY JOHN SIMPSON, AND OTHERS. I BELIEVE IT  
23 WAS THE INTENT OF OUR TASK FORCE TO ESSENTIALLY SAY  
24 THAT. I BELIEVE THE LANGUAGE THAT WE PUT IN IN THE  
25 FIRST PLACE WOULD HAVE COVERED THIS; BUT IF PEOPLE ARE



1 MORE COMFORTABLE WITH LANGUAGE, I'M SURE OUR TASK FORCE  
2 IS NEUTRAL ON THIS ISSUE.

3 ANY DISCUSSION ABOUT (D)(3) AND (4)?

4 MS. SAMUELSON: I HAVE A QUESTION. CAN YOU  
5 JUST SUMMARIZE WHAT IT IS THAT MAKES THE TASK FORCE  
6 CONCLUDE THAT THIS WILL NOT CREATE ANY DISINCENTIVES TO  
7 DEVELOPMENT OF BREAKTHROUGH THERAPIES BECAUSE OF THE  
8 PRICING?

9 DR. PENHOET: IT MAY PROVIDE A MODEST  
10 DISINCENTIVE. I THINK THAT'S ONE OF THE PRICES THAT  
11 WILL BE PAID FOR THIS; HOWEVER, THIS IS FOR PURCHASES  
12 ONLY BY PUBLIC AGENCIES IN THE STATE OF CALIFORNIA. IT  
13 DOESN'T REFER TO ANYTHING IN THE REST OF THE WORLD.  
14 AND I THINK, AS A PRACTICAL MATTER, THE MEDICARE  
15 PROGRAMS WITHIN -- MEDICAID PROGRAMS WITHIN THE STATE  
16 IN GENERAL TODAY ARE RECEIVING SIMILAR PRICING TO THE  
17 FEDERAL GOVERNMENT, SO IT MAY NOT REPRESENT A DRAMATIC  
18 CHANGE IN THE CURRENT SALES POLICIES OF COMMERCIAL  
19 ORGANIZATIONS IN THESE FIELDS, BUT IT DOES CODIFY HERE  
20 THAT THAT WILL BE THE CASE IN THE FUTURE. UNDER SOME  
21 CIRCUMSTANCES, IT'S POSSIBLE THAT ANY RESTRICTIONS OF  
22 LICENSEES WILL CREATE A BURDEN WHICH THEY FIND  
23 UNACCEPTABLE.

24 AFTER LOTS OF DISCUSSIONS AND HEARING FROM A  
25 NUMBER OF ORGANIZATIONS, WE DID COME UP WITH THIS

1 LANGUAGE. MOST THERAPY COMPANIES, AT LEAST TODAY, DO  
2 HAVE PROGRAMS IN PLACE FOR DEALING WITH THE NEEDS OF  
3 UNINSURED PATIENTS, PROVIDING FREE GOODS TO THOSE  
4 PATIENTS. AND I SHOULDN'T SPEAK FOR YOU, JEFF, BUT I  
5 THINK JEFF IS VERY FAMILIAR WITH THAT COMMUNITY AND  
6 WHAT THEY DO. AND THE GROUP OF US DECIDED TO LEAVE IT  
7 UP TO THE LICENSEE, TO THE GRANTEEES AND THEIR  
8 LICENSEES, TO COME UP WITH CREATIVE SOLUTIONS HOW THEY  
9 WOULD DO THAT RATHER THAN BEING MORE PROSCRIPTIVE ABOUT  
10 THAT.

11 THESE TWO REQUIREMENTS ARE AN EXTRA BURDEN ON  
12 LICENSEES. YOU CAN'T GET AROUND THAT, BUT WE BELIEVE  
13 THAT THIS IS A COMPROMISE. WE DID NOT GET ANY FEEDBACK  
14 FROM COMPANIES, BY THE WAY, FOCUSED ON THIS ISSUE IN  
15 REAL TIME OR -- I THINK MOST COMPANIES WE'VE TALKED TO  
16 HAVE ASSUMED THAT THIS IS A REASONABLE COMPROMISE. I  
17 SHOULDN'T SPEAK FOR OTHER COMPANIES. PERHAPS THOSE OF  
18 YOU WHO ARE ON THIS BOARD WHO ARE COMPANY  
19 REPRESENTATIVES MIGHT WANT TO SPEAK TO THE ISSUE.

20 MS. SAMUELSON: I GUESS I'D JUST LIKE TO SAY  
21 THAT ANY ADDITIONAL DISINCENTIVE TO BREAKTHROUGH -- THE  
22 URGENT DEVELOPMENT OF BREAKTHROUGH THERAPIES AS FAST AS  
23 POSSIBLE IS OF CONCERN TO ME. AND I'M INTERESTED IN  
24 JEFF'S ASSESSMENT ON THAT.

25 DR. PENHOET: I APPRECIATE YOUR CONCERN.

1     THERE WERE A NUMBER OF PROPOSALS THAT WE GO MUCH  
2     FURTHER THAN THIS TO MAKE THEM, QUOTE, UNQUOTE,  
3     AFFORDABLE, ETC.  AND WE WORKED TO FIND A REASONABLE  
4     MIDDLE GROUND TO WHICH WE'VE NOT HAD A LOT OF  
5     COMMERCIAL OBJECTION, BUT THAT'S WHERE WE ARE, JOAN.

6             MS. SAMUELSON:  IN A PERFECT WORLD WE WOULD  
7     HAVE QUICKLY DEVELOPED VERY CHEAP THERAPIES.  BUT AS A  
8     PATIENT WAITING URGENTLY FOR EFFECTIVE THERAPIES IN  
9     PARKINSON'S, I PERSONALLY HAVE DECIDED THAT I WOULD  
10    FIRST TACKLE AVAILABILITY TO ANYONE AT ANY PRICE AND  
11    THEN TACKLE PRICING.  AND IF THIS IS AN ADDITIONAL  
12    DISINCENTIVE, I'D LIKE TO DRILL DOWN ON THAT A BIT TO  
13    KNOW WHAT WE'RE REALLY DOING.  I BELIEVE IN CHEAP  
14    PRICES AS MUCH AS SENATOR ORTIZ AND OTHERS.  I WOULD  
15    LOVE TO HAVE THEM, BUT I THINK WE SHOULD KNOW WHAT  
16    WE'RE DOING.

17            DR. PENHOET:  WELL, IN THE MAJOR CASE WE'RE  
18    FOLLOWING THE LEAD OF THE FEDERAL GOVERNMENT.  IN THE  
19    PRIMARY CASE OF PRICING, WE'RE FOLLOWING THE LEAD OF  
20    THE FEDERAL GOVERNMENT IN THIS PROPOSAL.

21            MS. SAMUELSON:  WHICH YOU SAID WAS THE  
22    LOWEST, THEY GET THE LOWEST PRICES ALREADY.

23            DR. PENHOET:  THEY DO.  SO WE WOULD NOT BE  
24    DISADVANTAGED WITH RESPECT TO THE FEDERAL GOVERNMENT,  
25    BUT WE WOULD NOT BE LOWER THAN THE FEDERAL GOVERNMENT

1       EITHER.  THAT'S WHAT THIS SAYS.

2               DR. NOVA:  THE REALITY IS THAT THE MEDICAID  
3       IS BELOW WHAT'S VIABLE FOR A COMPANY.  IT'S NOT EVEN  
4       BREAKEVEN, SO WE AVOID IT LIKE THE PLAGUE.

5               MS. SAMUELSON:  SPEAK A LITTLE LOUDER.

6               DR. NOVA:  I'M AGREEING WITH YOU, JOAN.  I'M  
7       AGREEING THAT IT IS DEFINITELY A DISINCENTIVE TO  
8       COMPANIES LIKE THIS.  I WISH I WAS RUNNING A NONPROFIT;  
9       BUT IN A PROFIT WORLD, IT IS A DISINCENTIVE FOR IT TO  
10      BE THE MEDICAID AND COMPANIES WOULD AVOID THAT.  I  
11      THINK IT SHOULD -- WHAT I LIKE ABOUT THE ORIGINAL  
12      LANGUAGE IS THAT IT'S AT LEAST VIABLE FOR A COMPANY AND  
13      NOT BELOW.

14              MR. SHEEHY:  I WOULD JUST MAKE THE POINT THAT  
15      BECAUSE WE'RE BUILDING THIS IN AT THE FRONT END, THAT  
16      THEIR PRICING MODELS WILL REFLECT THIS REALITY.  SO THE  
17      FACT THAT THERE'S NO MYSTERY -- I PERSONALLY DON'T  
18      BELIEVE THIS WOULD BE A DISINCENTIVE BECAUSE I THINK  
19      THE FACT THAT WE BUILT IT IN AT THE FRONT END, THAT  
20      COMPANIES WILL BUILD THIS INTO THEIR PRICING MODELS.  
21      AND ALL THIS ASSURES IS THAT WE GET THE BEST PRICE FOR  
22      THE PEOPLE OF CALIFORNIA THAT THEY'RE PROVIDING.  IF  
23      THEY CAN'T MAKE THE PROFIT ON THE FEDERAL MEDICAID  
24      PRICE AND GIVE IT TO CALIFORNIA AT THAT PRICE, AND THEY  
25      WON'T SELL IT AT THAT PRICE.  WE'RE NOT DICTATING EXACT

1 DOLLAR PRICE THAT THEY'RE GOING TO DO. WE'RE JUST  
2 ASKING FOR SOME EQUITY IN PRICING. THIS IS NOT A  
3 FORCED PRICING. IT'S AN EQUITY PRICING REQUIREMENT.

4 IN TERMS OF THE PLANS, WE'RE LEAVING THE  
5 DEVELOPMENT OF THOSE PLANS UP TO THE COMPANIES  
6 THEMSELVES, AND I DON'T THINK THAT WILL BE A  
7 DISINCENTIVE EITHER.

8 DR. PENHOET: TO BE CLEAR, THIS DOES NOT  
9 SPEAK TO THE COMMERCIALIZATION OF THESE PRODUCTS  
10 ANYWHERE IN THE WORLD OUTSIDE CALIFORNIA. IT'S ONLY TO  
11 PUBLICLY FUNDED CALIFORNIA ORGANIZATIONS.

12 DR. LOVE: I THINK I WOULD WEIGH IN VERY  
13 CONSISTENT WITH WHAT JEFF JUST SAID. I THINK PEOPLE  
14 WILL KNOW WHAT THEY'RE GOING UP AGAINST, BE ABLE TO  
15 PLAN WHAT THEY'RE UP AGAINST IN THIS CIRCUMSTANCE. I  
16 THINK THERE ARE SOME THINGS THAT WE COULD DO, JOAN,  
17 WHICH WOULD BE NONSTARTERS FOR COMPANIES, BUT I THINK  
18 THIS IS NOT A NONSTARTER, AT LEAST FROM MY VIEW.

19 MS. SAMUELSON: I HOPE YOU'RE RIGHT. I'M  
20 HEARING FROM TINA THAT SOME COMPANIES MAY BE  
21 DISCOURAGED. IN PARKINSON'S WE'RE TOLD ALL THE TIME  
22 THAT IT'S TOO SMALL A MARKET FOR IT TO BE  
23 COST-EFFECTIVE TO GO INTO THE FIELD. THAT'S A BIG  
24 PROBLEM, AND I'M NOT HEARING HOW THIS IS GOING TO BE  
25 ALLEVIATED BECAUSE WE WERE LOOKING TO THE 71 MONEY TO

1 MAKE THE DIFFERENCE.

2 DR. PENHOET: I DO BELIEVE, FIRST OF ALL,  
3 THESE ARE PROBABLY SOMEWHERE DOWN THE ROAD. I DO  
4 THINK, LIKE ALL ASPECTS OF THIS, WE WOULD HAVE AN  
5 OPPORTUNITY TO REVISIT THIS IF THIS BECAME A BURDEN TO  
6 WHICH NO COMPANIES WOULD SIGN UP. SO THAT WILL ALWAYS  
7 BE POSSIBLE.

8 DR. PRIETO: I'D JUST LIKE TO REITERATE SOME  
9 OF WHAT JEFF HAD SAID AND SPEAK TO MY OWN PERSPECTIVE.  
10 THIS DID NOT DICTATE WHAT THE PRICING WILL BE. IT  
11 MERELY SPECIFIES THAT CALIFORNIA WILL GET THE BEST  
12 PRICE OUT THERE, AND IT DOES GIVE PREDICTABILITY TO  
13 ANYONE DEVELOPING A THERAPY OR TREATMENT THAT FOR THIS  
14 PARTICULAR POPULATION, THIS PARTICULAR SET OF BUYERS  
15 WILL GET A CERTAIN PRICE. AND YOU CAN SET THAT PRICE,  
16 AND YOU WILL BE ABLE IN THE COMMERCIAL MARKET TO SET A  
17 HIGHER PRICE. WE'RE NOT DICTATING AT EITHER LEVEL WHAT  
18 THAT PRICE IS GOING TO BE, JUST THAT WE GET, AT LEAST  
19 THE PEOPLE OF CALIFORNIA, GET THE BEST DEAL THAT'S OUT  
20 THERE.

21 AND SPEAKING AS PART OF A MEDICAL GROUP THAT  
22 GETS A SUBSTANTIAL PORTION OF OUR INCOME FROM PUBLIC  
23 FUNDING IN CALIFORNIA, WE FIGURE THAT INTO OUR  
24 CALCULATIONS, WHAT OUR PRICING TO COMMERCIAL INSURERS  
25 AND PATIENTS COMING FROM THOSE WILL BE VERSUS WHAT WE

1 KNOW WE'RE GOING TO GET FROM PUBLIC SOURCES. YES, WE  
2 GET CONSIDERABLY LESS FROM PUBLIC SOURCES, AND  
3 SOMETIMES WE LOSE MONEY ON SOME OF THE TREATMENTS WE  
4 PROVIDE, AND WE FIGURE THAT INTO OUR CALCULATIONS AND  
5 RUN THE NUMBERS AND DECIDE WHAT WE NEED TO CHARGE IN  
6 ORDER TO KEEP THE DOORS OPEN.

7 DR. PENHOET: ANY OTHER COMMENTS FROM THE  
8 BOARD? COMMENTS FROM THE AUDIENCE?

9 MR. TAYAG: GOOD MORNING. MY NAME IS JOE  
10 TAYAG. I'M FROM THE GREENLINING INSTITUTE. WE'RE A  
11 MULTI-ETHNIC COALITION OF OVER 40 ORGANIZATIONS  
12 THROUGHOUT THE STATE, INCLUDING MEXICAN-AMERICAN  
13 POLITICAL ASSOCIATION, THE FIRST AME CHURCH, THE  
14 SOUTHEAST ASIAN CENTER, AS WELL AS (UNINTELLIGIBLE)  
15 COMMUNITY CLINIC.

16 WE WANTED TO TAKE THIS OPPORTUNITY TO COMMEND  
17 AND RECOGNIZE THE WORK OF THE IP TASK FORCE, ESPECIALLY  
18 INCLUDING PROVISIONS IN SECTION H WHICH RECOGNIZE  
19 ISSUES OF ACCESS TOWARDS LOW INCOME AND THE UNINSURED  
20 OF CALIFORNIA, AS WELL AS TRYING TO GUARANTEE A REVENUE  
21 STREAM BACK INTO THE STATE. WE WANT TO SHOW OUR FULL  
22 SUPPORT FOR THE PROPOSED LANGUAGE. WE WERE LOOKING FOR  
23 A LOT MORE CLARITY, AND WE WOULD LIKE TO SEE THAT WITH  
24 THE FEDERAL MEDICAID PRICES, AS WELL AS WE WOULD LIKE  
25 TO URGE THE ICOC TO PERHAPS CONSIDER EXTENDING THAT

1 SAME GUARANTEE TOWARDS COMMUNITY HEALTH PROGRAMS, AS  
2 WELL AS -- COUNTY HEALTH PROGRAMS AND COMMUNITY HEALTH  
3 CLINICS. THANK YOU.

4 MR. SIMPSON: JOHN SIMPSON FROM THE  
5 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I'M A  
6 GREAT BELIEVER IN SIMPLE ENGLISH, AND I WOULD HAVE  
7 PREFERRED TO HAVE SEEN SIMPLY BEST U.S. PRICE. AGAIN,  
8 IT'S A QUESTION OF WHAT EQUITY WOULD BE. WE WOULD GET  
9 THE BEST PRICE THAT ANYONE ELSE IN THE COUNTRY IS  
10 GETTING. THIS PROPOSED LANGUAGE SEEMS TO BE A  
11 REASONABLE COMPROMISE. BUT BEST PRICE SEEMS EVEN  
12 BETTER.

13 MS. STREITZ: I THINK THERE'S AN UNINTENDED  
14 CONSEQUENCE OF THE WORDING OF THE FIRST SENTENCE. THE  
15 WAY IT'S WORDED RIGHT NOW, IF A POTENTIAL LICENSEE  
16 GIVES US AN ACCESS PLAN, THEN WE HAVE TO GIVE THEM A  
17 LICENSE AND IT HAS TO BE EXCLUSIVE. AND THERE MAY BE  
18 CASES WHERE IT SHOULDN'T BE EXCLUSIVE. SO I THINK THE  
19 WAY TO FIX THAT IS TO STICK THE WORD "ONLY" IN AFTER  
20 DIAGNOSTICS, SO IT WOULD READ GRANTEE ORGANIZATIONS  
21 SHALL GRANT EXCLUSIVE LICENSES INVOLVING CIRM-FUNDED  
22 PATENTED INVENTIONS RELEVANT TO THERAPIES AND  
23 DIAGNOSTICS ONLY TO ORGANIZATIONS WITH PLANS TO PROVIDE  
24 ACCESS, BLAH, BLAH, BLAH.

25 DR. PENHOET: WILL YOU ADD THAT LANGUAGE,



1 PLEASE?

2 MR. REYNOLDS: JESSE REYNOLDS FROM THE CENTER  
3 FOR GENETICS AND SOCIETY. I'D LIKE TO BUNDLE A COUPLE  
4 OF QUICK COMMENTS.

5 FIRST, THE DEVELOPMENT OF THE INTELLECTUAL  
6 PROPERTY POLICY THAT I'VE FOLLOWED AND TRIED TO BE  
7 ACTIVE IN HAS BEEN ONE THAT'S GROWN INCREASINGLY  
8 INCLUSIVE AND PARTICIPATORY. AND I'D LIKE TO THANK DR.  
9 PENHOET AND THE REST OF THE TASK FORCE FOR THAT.

10 THE PROPOSAL BEFORE THE BOARD TODAY APPEARS  
11 TO MEET A LOT OF OUR KEY CONCERNS THAT WE'VE BEEN  
12 BRINGING UP ALONG WITH OTHER GROUPS SUCH AS THE  
13 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS AS WELL AS  
14 SENATOR ORTIZ. AND THIS IS A KEY ONE. AND I URGE THE  
15 BOARD TO MAINTAIN THIS EQUITABLE PRICE STRUCTURE FOR  
16 CALIFORNIANS, PUBLIC-FUNDED HEALTHCARE. THANK YOU.

17 MS. KU: KATHY KU FROM STANFORD UNIVERSITY.  
18 WE WERE WONDERING WHETHER FOR THE UNINSURED YOU HAVEN'T  
19 IMPLICIT -- IMPLIED INDIGENT UNINSURED. AND IF THAT'S  
20 WHAT YOU MEAN, WE SUGGEST YOU ADD THAT WORD.

21 DR. PENHOET: COULD YOU GIVE US A LITTLE MORE  
22 COLOR AROUND THAT COMMENT, PLEASE? UNINSURED IS AS  
23 BROAD A POPULATION AS INDIGENT. IS THERE A FAIR  
24 DEFINITION OF INDIGENT THAT WE COULD COUNT ON FOR THIS  
25 PURPOSE?

1 MS. KU: I DON'T HAVE A DEFINITION OF  
2 INDIGENT, BUT WE WERE THINKING OF PEOPLE WHO MIGHT BE  
3 CONSULTANTS WHO DON'T HAVE HEALTHCARE, THEY'RE  
4 UNINSURED, PERHAPS BY CHOICE, BUT THEY ARE NOT  
5 NECESSARILY POOR.

6 CHAIRMAN KLEIN: I WOULD SUPPORT THAT  
7 COMMENT. CERTAINLY THE GOAL IS TO ACCESS THE INDIGENT  
8 UNINSURED. THERE ARE WEALTHY PEOPLE WHO CHOOSE TO  
9 SELF-INSURE THEMSELVES AND NOT COVER THEIR OWN HEALTH  
10 INSURANCE. THAT'S NOT THE GOAL HERE.

11 DR. PENHOET: IS THERE A GENERAL SENTIMENT TO  
12 ADD THE WORD "INDIGENT"?

13 MR. SHEEHY: CAN WE GET A BENCHMARK? I THINK  
14 THE WORD "INDIGENT" IS TOO INDEFINITE. IS THERE A  
15 STANDARD BENCHMARK FOR, YOU KNOW -- ISN'T THERE AN  
16 INCOME MEASURE? CAN WE SAY SOME PERCENTAGE OF AN  
17 INCOME MEASURE?

18 DR. LOVE: I'M WONDERING IF WE NEED TO -- I  
19 THINK THE ISSUE REALLY IS IS CALIFORNIA BUYING IT OR  
20 NOT. IT'S NOT REALLY WHAT YOUR INCOME LEVEL IS. IS  
21 THE STATE OF CALIFORNIA STEPPING IN BECAUSE THE WHOLE  
22 POINT HERE, I THOUGHT, WAS TO MAKE SURE THAT THE STATE  
23 OF CALIFORNIA GETS THE BENEFIT.

24 DR. PENHOET: THERE ARE TWO ASPECTS OF THAT,  
25 DR. LOVE, AS YOU PROBABLY REMEMBER. ONE IS PRICING TO

1 PUBLICLY FUNDED. THAT'S A DIRECT BENEFIT TO THE STATE.  
2 THE INDIRECT BENEFIT TO THE STATE WOULD BE WHATEVER  
3 CREATIVE PLANS ORGANIZATIONS THEMSELVES COME UP WITH  
4 FOR ADDRESSING THE NEEDS OF UNINSURED. AND THE  
5 INTENTION WAS PEOPLE WHO OTHERWISE COULDN'T AFFORD  
6 THESE THERAPIES. SO IF INDIGENT IN SOME DEFINITION  
7 THAT WE'LL HAVE TO CRAFT THAT GETS TO THE SENTIMENT  
8 COVERS THAT, THEN I THINK THAT'S WHAT PEOPLE HAD IN  
9 MIND, NOT FUNDING THESE THERAPIES FOR WEALTHY PEOPLE  
10 WHO CHOOSE TO HAVE NO INSURANCE.

11 IF WE COULD USE THE WORD "INDIGENT" AS A  
12 PLACEHOLDER AND COME BACK WITH A FURTHER DEFINITION OF  
13 WHAT THAT MEANS, WOULD THAT BE ACCEPTABLE TO THE GROUP?  
14 OKAY. DO I HAVE A MOTION TO APPROVE THIS AS AMENDED?

15 MR. TAYMOR: I WOULD JUST LIKE TO SPEAK  
16 AGAINST THAT POINT. THOUGH THERE ARE SOME WEALTHY  
17 PEOPLE WHO CHOOSE NOT TO BE INSURED, THERE ARE IN THE  
18 STATE AND COUNTRY A LARGE NUMBER OF WORKING CLASS  
19 PEOPLE, MIDDLE-CLASS PEOPLE WHO ARE UNINSURED, NOT ABLE  
20 TO OBTAIN INSURANCE AT ANY REASONABLE COST. THERE'S A  
21 BREAKOUT IN THIS POLICY TO SUGGEST A PLAN SHOULD BE  
22 DEVELOPED TO TRY TO ADDRESS THEIR HEALTHCARE NEEDS FOR  
23 A SPECIFIC PRICING FLOOR FOR LOWER INCOME PEOPLE.

24 WITH RESPECT TO INDIGENTS, YOU HAVE A NUMBER  
25 OF BENCHMARKS YOU CAN USE, AND MEDICAID AND X PERCENT

1 OF MEDIAN INCOME AND SO FORTH. REALLY THINK SERIOUSLY  
2 ABOUT THE CONSEQUENCES FOR THE WORKING CLASS AND MIDDLE  
3 CLASS IN THE STATE WHO VOTED FOR THIS INITIATIVE WE  
4 WOULD BE DEPRIVING OF ITS BENEFIT.

5 MR. SHEEHY: I THINK HE'S GOT THE RIGHT  
6 POINT. IF PEOPLE ARE TRULY INDIGENT, THEY HAVE ACCESS  
7 TO PUBLIC PROGRAMS THAT WOULD PAY FOR THESE. SO I KIND  
8 OF THINK WE SHOULD STRIKE INDIGENT. WE'RE ASKING WHAT  
9 COMPANY IN THEIR RIGHT MIND WOULD DEVELOP A PLAN FOR  
10 ACCESS FOR UNINSURED PEOPLE WHO COULD PAY FOR THEIR  
11 THERAPIES. IT'S KIND OF IMPLICIT IN THE NOTION THAT  
12 THEY'RE GOING TO PROVIDE THESE -- THAT THEY'RE GOING TO  
13 GO WITH THE PLAN FOR PEOPLE WHO CAN'T QUITE AFFORD  
14 THEM, BUT CAN'T AFFORD INSURANCE EITHER.

15 DR. PENHOET: YOU MAKE AN INTERESTING POINT.  
16 WE MAY HAVE DRIVEN THIS TO SUCH A SMALL NUMBER OF  
17 PEOPLE IT LOSES FORCE. AND WE ARE GOING TO DEPEND ON  
18 THE INVENTIVENESS OF THE GRANTEE AND THE LICENSEE TO  
19 COME UP WITH PLANS THAT ADDRESS --

20 MR. SHEEHY: I THINK THEY CAN FIGURE THIS  
21 OUT. I THINK WE SHOULD PROBABLY LEAVE INDIGENT OUT.

22 DR. PENHOET: PERHAPS THE WEALTHY UNINSURED  
23 ARE SUCH A SMALL FRACTION, THAT WE SHOULDN'T BE OVERLY  
24 CONCERNED ABOUT THEM AT THIS MEETING.

25 CHAIRMAN KLEIN: I THINK THAT JOAN'S PRIOR

1 COMMENT IS IMPORTANT HERE. WE CAN'T SO BURDEN THE  
2 SYSTEM, THAT WE DON'T GET THE THERAPIES TO THE PATIENTS  
3 THAT NEED THEM. AND INDIGENT, I THINK, IS AN IMPORTANT  
4 CONCEPT. THERE ARE MANY INDIGENT WHO THEORETICALLY ARE  
5 COVERED BY PROGRAMS, BUT THERE ARE LARGE GAPS IN THAT  
6 COVERAGE ON A FUNCTIONAL, PRACTICAL BASIS. THAT IN THE  
7 AFFORDABLE HOUSING FIELD, WE'RE EXPOSED TO A LOT OF  
8 PEOPLE WHO ARE INDIGENT, QUALIFIED FOR VERY LOW-INCOME  
9 HOUSING, BUT ARE DRIVEN INTO BANKRUPTCY BECAUSE THEY  
10 CAN'T REALLY GET THEIR COVERAGE EVEN THOUGH  
11 THEORETICALLY MAYBE THEY'RE QUALIFIED FOR IT.

12 SO THE ISSUE HERE IS A BALANCING ONE. AND I  
13 LIKED THE VICE CHAIR'S SUGGESTION THAT WE COULD ADDRESS  
14 THE ISSUE OF INDIGENTS, HAVE THE WORD IN HERE, BUT TRY  
15 AND DEVELOP THAT DEFINITION; BUT WE NEED TO REALIZE  
16 THAT WHILE WE ARE REACHING FOR NEW AREAS, AS  
17 DR. KESSLER HAS SAID, AND EXPLORING THE ABILITY TO MAKE  
18 SURE PEOPLE WHO ARE INDIGENT ARE COVERED, THE QUESTION  
19 IS BY LEAVING IT UNQUALIFIED, WE MAY BE CREATING A MUCH  
20 LARGER CLASS THAN THE COMMERCIAL ENTITIES CAN ESTIMATE,  
21 PREDICT, AND BUDGET AND, THEREFORE, CREATE A MUCH MORE  
22 SIGNIFICANT DISINCENTIVE TO ACTUALLY DELIVERING  
23 THERAPIES THAN WE INTENDED.

24 DR. PRIETO: I'D RESPOND TO THAT. I'D SAY  
25 WE'RE PUTTING -- THIS LANGUAGE, AS IT CURRENTLY STANDS,

1 IS PUTTING THE BURDEN ON THOSE COMPANIES TO COME UP  
2 WITH THE PLAN AND DEFINE THOSE CLASSES. AND THEN WE  
3 WILL BE ABLE TO EVALUATE THOSE PLANS AND DETERMINE  
4 WHETHER THAT'S APPROPRIATE OR NOT, BUT I LIKE THE  
5 CONCEPT THAT CAME OUT OF THE TASK FORCE WHERE WE  
6 DECIDED DELIBERATELY TO PUT THE BURDEN OF CREATIVITY,  
7 IF YOU WILL, ON THE COMPANIES.

8 MR. SHEEHY: I REALLY, SINCE THIS IS A  
9 COMPANY BURDEN, I DON'T SEE THIS AS DISINCENTIVE. I  
10 ALSO AM VERY RELUCTANT TO LIMIT IT TO THE INDIGENT.  
11 AND THE BEST EXAMPLE OF A PROGRAM FOR PEOPLE WHO ARE  
12 UNINSURED IS THE FEDERALLY AND STATE FUNDED AIDS DRUG  
13 ASSISTANCE PROGRAM, WHICH RUNS UP, WHEN I ACCESSED IT,  
14 TO PEOPLE MAKING UP TO \$55,000 A YEAR BECAUSE THE  
15 THERAPIES ON A SLIDING SCALE, BECAUSE THE THERAPIES AT  
16 THAT TIME COST BETWEEN 15 AND 20,000, NOT COUNTING THE  
17 COST OF DIAGNOSTICS. SO WE DON'T KNOW WHAT THESE  
18 THERAPIES ARE GOING TO BE. WE DON'T KNOW WHAT THEY'RE  
19 GOING TO COST. WE DON'T KNOW HOW THEY'RE GOING TO BE  
20 DELIVERED.

21 I THINK THE BEST THING IS TO LEAVE A VERY  
22 BROAD REQUIREMENT THAT THE COMPANIES COME UP WITH A  
23 PLAN, BUT THEIR PLAN WILL BE TAILORED BOTH TO THE  
24 MARKET AND THE REALITY OF WHAT THEY DEVELOP.

25 DR. PENHOET: WE'RE NOT SPECIFYING IN ANY

1       DETAIL WHAT SHOULD BE IN THOSE PLANS.

2                   CHAIRMAN KLEIN:  THE CONCERN IS IF YOU DON'T  
3       KNOW WHO YOU'RE SUPPOSED TO SERVE AND YOU'RE INVESTING  
4       UP FRONT, FOUR, FIVE, OR EIGHT, OR TEN YEARS LATER,  
5       YOU'VE MADE AN INVESTMENT AND YOU'VE GOT AN UNKNOWN  
6       MARKET THAT YOU ARE SUPPOSED TO SUBMIT A PLAN FOR.  IT  
7       CREATES GRAVE UNCERTAINTY IN THE ECONOMIC PROJECTIONS  
8       YOU NEED TO ATTRACT THE CAPITAL TO GET THE WORK DONE TO  
9       DRIVE THE THERAPY FORWARD.

10                   NOW, THOSE UNCERTAINTIES RIGHT NOW AT THIS  
11       INITIAL STAGE, I WOULD SUGGEST, WE ARE BETTER OFF,  
12       SINCE WE'RE BREAKING NEW GROUND, KEEPING THOSE  
13       UNCERTAINTIES NARROW.  UPON REFLECTION WITH MORE  
14       INFORMATION IN FUTURE PERIODS, WE CAN EXPAND THIS  
15       DEFINITION, BUT RIGHT NOW TO TRY AND MAKE SURE WE DO  
16       DRIVE THERAPIES FORWARD, I THINK IT'S PART OF OUR  
17       OBLIGATION TO PATIENTS EVERYWHERE TO KEEP THEM NARROW.

18                   DR. PENHOET:  WE ARE IN DANGER OF HAVING THIS  
19       DISCUSSION RUN UNTIL 6 O'CLOCK TONIGHT.

20                   MS. FEIT:  I WOULD OBJECT TO THE USE OF THE  
21       WORD "INDIGENT."  THOSE OF US WHO WORK WITH THOSE  
22       PATIENTS EVERY DAY, WE QUALIFY THEM IMMEDIATELY FOR  
23       PUBLIC ASSISTANCE PROGRAMS.  IT'S THE UNINSURED THAT  
24       EVERYBODY IS CONCERNED ABOUT.  AND THE COMMENT EARLIER  
25       BY THE GENTLEMAN ABOUT THE WORKING POOR IS THE CONCERN

1 IN THE ENTIRE COUNTRY. SO I WOULD OBJECT TO THE  
2 WORD -- INSERTING INDIGENT IN ANY OF THE LANGUAGE.

3 MR. GOLDBERG: WITH ALL DUE RESPECT, MARCY,  
4 THE DATA THAT HAS BEEN DEVELOPED AND REVIEWED IN  
5 CONGRESS INDICATES, AND I AGREE WITH YOUR INTENT, ABOUT  
6 25 PERCENT OF THE UNINSURED IN THE UNITED STATES,  
7 THAT'S 10 MILLION OF THE 40 MILLION, ACTUALLY ARE  
8 SELF-INSURED AND QUALIFY FOR HEALTH INSURANCE, BUT  
9 CHOOSE, AS A PERSONAL MATTER, NOT TO DO IT. I JUST  
10 WANT TO MAKE SURE THAT WE DON'T CROSS-SUBSIDIZE THEM.

11 DR. PENHOET: CAN I USE THE SAME PROCEDURE WE  
12 USED BEFORE? I'D LIKE TO HAVE SOMEBODY THERE CALL THE  
13 QUESTION AND APPROVE THIS LANGUAGE WITHOUT THE WORD  
14 "INDIGENT," AND THEN HAVE A SECOND VOTE OF WHETHER OR  
15 NOT WE SHOULD ADD THE WORD "INDIGENT." SO IS SOMEBODY  
16 PREPARED TO MAKE THAT MOTION?

17 MR. SHEEHY: I MAKE THE --

18 DR. LOVE: SO MOVED.

19 MR. SHEEHY: AND I SECOND.

20 DR. PENHOET: MOTION BY DR. LOVE, SECONDED BY  
21 JEFF SHEEHY. ALL IN FAVOR OF THIS PARAGRAPH WITHOUT  
22 THE WORD "INDIGENT" AS INDICATED HERE. ALL IN FAVOR  
23 SAY AYE. OPPOSED?

24 I THINK WE NEED A ROLL CALL VOTE, MELISSA.

25 MS. KING: PAUL JENNINGS.



1 DR. JENNINGS: YES.  
2 MS. KING: ROBERT BIRGENEAU.  
3 DR. BIRGENEAU: AYE.  
4 MS. KING: DAVID MEYER.  
5 DR. MEYER: YES.  
6 MS. KING: SUSAN BRYANT.  
7 DR. BRYANT: NO.  
8 MS. KING: MARCY FEIT.  
9 MS. FEIT: YES.  
10 MS. KING: MICHAEL FRIEDMAN.  
11 DR. FRIEDMAN: YES.  
12 MS. KING: MICHAEL GOLDBERG.  
13 MR. GOLDBERG: NO.  
14 MS. KING: FRANCIS MARKLAND.  
15 DR. MARKLAND: NO.  
16 MS. KING: ED HOLMES.  
17 DR. HOLMES: YES.  
18 MS. KING: DAVID KESSLER.  
19 DR. KESSLER: YES.  
20 MS. KING: BOB KLEIN.  
21 CHAIRMAN KLEIN: NO.  
22 MS. KING: SHERRY LANSING.  
23 MS. LANSING: YES.  
24 MS. KING: GERALD LEVEY. TED LOVE.  
25 DR. LOVE: YES.

1 MS. KING: TINA NOVA.  
2 DR. NOVA: NO.  
3 MS. KING: ED PENHOET.  
4 DR. PENHOET: YES.  
5 MS. KING: PHIL PIZZO.  
6 DR. PIZZO: NO.  
7 MS. KING: CLAIRE POMEROY.  
8 DR. POMEROY: YES.  
9 MS. KING: FRANCISCO PRIETO.  
10 DR. PRIETO: YES.  
11 MS. KING: JOHN REED.  
12 DR. REED: YES.  
13 MS. KING: JOAN SAMUELSON.  
14 MS. SAMUELSON: NO.  
15 MS. KING: DAVID SERRANO-SEWELL. JEFF  
16 SHEEHY.  
17 MR. SHEEHY: YES.  
18 MS. KING: JONATHAN SHESTACK.  
19 MR. SHESTACK: YES.  
20 MS. KING: OSWALD STEWARD.  
21 DR. STEWARD: YES.  
22 MS. KING: LEON THAL.  
23 DR. THAL: YES.  
24 MS. KING: JANET WRIGHT.  
25 DR. WRIGHT: YES.

1 DR. PENHOET: THE MOTION CARRIES. DOES  
2 SOMEONE WANT TO MAKE A SECOND MOTION TO ADD TO WHAT WE  
3 JUST APPROVED THE WORD "INDIGENT"?  
4 MR. GOLDBERG: SO MOVED.  
5 DR. PENHOET: MOTION BY MICHAEL GOLDBERG.  
6 SECOND?  
7 DR. PIZZO: SECOND.  
8 DR. PENHOET: PHIL PIZZO. CAN WE VOTE ON  
9 ADDING THE WORD "INDIGENT" TO THE PARAGRAPH WE JUST  
10 APPROVED? ALL IN FAVOR.  
11 DR. JENNINGS: EARLIER YOU SAID THAT INDIGENT  
12 WAS GOING TO BE A PLACEHOLDER FOR MORE TERMINOLOGY TO  
13 BE DEFINED LATER. IS THAT STILL THE CASE?  
14 DR. PENHOET: I THINK EITHER WAY WE HAVE TO  
15 DO MORE OF THAT WORK. UNINSURED WILL ALSO BE SUBJECT  
16 TO SOME FURTHER AND MORE PRECISE DEFINITION. SO I  
17 THINK WE'RE GOING TO HAVE TO DEFINE EITHER OR BOTH OF  
18 THESE TERMS MORE PRECISELY.  
19 DR. JENNINGS: IN THAT SENSE, IS THAT WHAT  
20 WE'RE VOTING ON? THAT'S MY QUESTION. ARE WE VOTING ON  
21 THAT AS A SPECIFIC WORD OR AS A PLACEHOLDER?  
22 DR. POMEROY: WE NEED TO SEE WHAT WE'RE  
23 VOTING ON IN WRITING. I WOULD LIKE TO SEE WHAT WE'RE  
24 VOTING ON IN WRITING.  
25 DR. PENHOET: OKAY.

1 DR. POMEROY: IN A LARGE ENOUGH FONT THAT WE  
2 CAN READ IT.

3 DR. BIRGENEAU: I DIDN'T HEAR A SENSIBLE  
4 RESPONSE TO JEFF SHEEHY'S POINT, WHICH I THINK WAS VERY  
5 WELL TAKEN, WHICH IS THAT IF THE COST OF A THERAPY IS  
6 \$15,000 A YEAR AND YOUR FAMILY INCOME IS \$30,000 A  
7 YEAR, YOU'RE TECHNICALLY NOT INDIGENT. AND SO INDIGENT  
8 WOULD EXCLUDE YOU FROM THIS, WHICH I THINK IS NOT  
9 REASONABLE.

10 MR. SHESTACK: WHO MADE THE MOTION TO  
11 ADVOCATE FOR IT? I DON'T UNDERSTAND WHY WE WOULD WANT  
12 TO DO IT. WHAT ARE YOU TRYING TO ACCOMPLISH BY THIS  
13 MOTION EXACTLY?

14 MR. GOLDBERG: BY ADDING THE TERM "INDIGENT"?

15 MR. SHESTACK: YEAH.

16 MR. GOLDBERG: TO DISTINGUISH BETWEEN THOSE  
17 PEOPLE WHO CAN AFFORD, BUT ELECT NOT TO HAVE INSURANCE  
18 FROM THOSE WHO DON'T. THAT'S ALL.

19 MR. SHEEHY: WELL, WHY DON'T WE SAY THAT?  
20 I'M HAPPY --

21 MR. SHESTACK: THE REAL CONCERN IS THE  
22 PEDIATRIC POPULATION, THE UNINSURED PEDIATRIC  
23 POPULATION. AND SO IT SEEMS TO ME LIKE THERE MIGHT BE  
24 A BETTER WAY TO SAY WHAT YOU WANT. WORKS THE MARGINS A  
25 LITTLE BETTER.

1                   MR. SHEEHY: I WOULD ADD I JUST CAN'T IMAGINE  
2   A COMPANY PRESENTING A PLAN FOR UNINSURED CALIFORNIANS  
3   THAT WOULD INCLUDE PEOPLE WHO COULD PAY THEM. WHY  
4   WOULD THEY GIVE IT AWAY TO PEOPLE WHO COULD PAY THEM?  
5   THE REQUIREMENT HERE ISN'T TO GIVE AWAY DRUGS TO PEOPLE  
6   WHO CAN PAY FOR THEM. IT'S TO MAKE SOME PROVISION FOR  
7   THOSE WHO CANNOT PAY FOR THEM, BUT DO NOT HAVE  
8   INSURANCE. AND THOSE ALMOST BY DEFINITION, FOR THE  
9   MOST PART, ARE NOT GOING TO BE INDIGENT. THIS INDIGENT  
10  PROVISION IS REALLY A NARROWING OF THE ACCESS PROVISION  
11  DRAMATICALLY AND TAKES US AWAY FROM WHAT WE SAID WE  
12  WERE GOING TO DO.

13                  DR. HALL: CAN I JUST MAKE A PROCEDURAL  
14  POINT? WE HAVE A LONG DAY. WE HAVE LOTS OF THINGS TO  
15  DISCUSS. AND MY SUGGESTION IS THAT FOR ISSUES LIKE  
16  THIS, WE HAVE 270 DAYS TO COME TO A MORE FACT-FILLED  
17  AND MORE INFORM OURSELVES, TO DISCUSS MANY OF THE  
18  INTRICACIES OF THIS. I DON'T THINK ANYTHING IS GOING  
19  TO HAPPEN IN 270 DAYS THAT WOULD BE RELEVANT TO THIS.  
20  AND SO I WOULD LIKE TO SUGGEST THAT WE APPLY THAT  
21  LITMUS TEST TO THE DISCUSSIONS.

22                  WE HAVE ETHICS COMING UP, AND WE HAVE GRANTS  
23  ADMINISTRATION POLICY, AND OTHER THINGS. AND SO I  
24  THINK IF WE ARE GOING BE ABLE TO SEND OUR GRANTS OUT,  
25  WE NEED TO GET THROUGH THIS, AND MY SUGGESTION WOULD BE

1 TO POSTPONE AS MANY OF THESE DISCUSSIONS IN GOOD WILL  
2 AS POSSIBLE IF THEY DON'T HAVE IMMEDIATE CONSEQUENCES.

3 DR. KESSLER: COULD I JUST ASK A POINT OF  
4 CLARIFICATION? THE 270 DAYS, WHAT ARE WE ALLOWED TO  
5 AMEND? AFTER WE PUT OUT A PROPOSE, THEN WE HAVE TO  
6 BASE IT ON COMMENTS, DON'T WE? WE'RE NOT JUST FREE TO  
7 AMEND OR ARE WE?

8 MR. HARRISON: YOU CAN AMEND, ALTHOUGH  
9 DEPENDING UPON THE NATURE OF THE AMENDMENTS, IT WILL  
10 RESTART THE PUBLIC COMMENT PERIOD. IF THERE ARE  
11 SUBSTANTIAL AMENDMENTS, FOR EXAMPLE, YOU START A NEW  
12 45-DAY PUBLIC COMMENT PERIOD.

13 DR. KESSLER: SO THERE'S -- I'M NOT SURE HOW  
14 THIS WORKS.

15 DR. HALL: LET ME JUST COMMENT. OUR MEDICAL  
16 AND ETHICAL STANDARDS, REMEMBER WE HAVE AN INTERIM  
17 POLICY IN PLACE. AND THEN WE WORK OVER SOME MONTHS TO  
18 DEVELOP A POLICY, WHICH WE ARE GOING TO TALK ABOUT  
19 LATER, WHICH IS A DRAFT POLICY THAT WILL BE SENT OUT  
20 FOR PUBLIC COMMENT. AS I UNDERSTAND IT, THERE'S NO  
21 REASON NOT TO BE ABLE TO HAVE -- WE NEED AN INTERIM  
22 POLICY IN ORDER TO MOVE AHEAD, BUT WE ALSO HAVE TIME TO  
23 DEVELOP A DRAFT THAT WE CAN USE FOR PUBLIC COMMENT AND  
24 OAL. SO WE ARE AT AN EARLIER STAGE IN THIS DISCUSSION  
25 THAN WE ARE WITH THE ETHICS. AND MY POINT IS WE CAN,

1 IF WE WISH, ASK -- ENACT THIS AS AN INTERIM GUIDELINE  
2 AND THEN SPEND MORE TIME DRAFTING REGULATIONS THAT WE  
3 WOULD PUT OUT FOR PUBLIC COMMENT FOR THE OAL.

4 DR. KESSLER: AGAIN, WHAT WE'RE -- THE  
5 SIGNIFICANCE OF A VOTE TODAY IS WHAT?

6 DR. PENHOET: THIS WILL BE THE INTERIM POLICY  
7 FOR USE FOR THE TRAINING GRANTS.

8 DR. KESSLER: THIS IS NOT THE PROPOSED.

9 DR. HALL: UNTIL WE GET THE FINAL POLICY  
10 ENACTED, THIS IS WHAT WILL BE IN FORCE. AT THE OUTSET,  
11 THIS WILL BE IN FORCE FOR 270 DAYS, NOT LONGER. SO TO  
12 TRY TO GIVE SOME PERSPECTIVE TO SOME OF THE DISCUSSIONS  
13 THAT WE HAVE.

14 DR. KESSLER: AND THEN WE DO A PROPOSED.

15 DR. HALL: DURING THAT PERIOD OF TIME, WE  
16 HAVE THE OPPORTUNITY TO ADD TO THIS DRAFT. OKAY. THEN  
17 SUBMIT TO OAL, OR AT LEAST NOTICE IT, I'M SORRY, THEN  
18 HAVE A 45-DAY COMMENT PERIOD.

19 DR. KESSLER: SO WE'RE NOT NOTICING THESE  
20 YET.

21 DR. HALL: SO WE CAN HAVE ANOTHER SHOT AT IT  
22 BEFORE IT'S NOTICED.

23 DR. KESSLER: SO YOU'RE FREE TO AMEND UNTIL  
24 YOU NOTICE.

25 DR. PENHOET: IF I MAY USE THE CHAIRMAN'S

1 PREROGATIVE, MY OWN VIEW IS THAT INDIGENT IS A LOADED  
2 WORD, AND THAT WE HAVE TO DEFINE UNINSURED. IF WE  
3 DON'T PUT IT IN, THEN WE HAVE TO DEFINE INDIGENT. IF  
4 WE DO PUT IT IN, SO SPEAKING FOR MYSELF, I WOULD PREFER  
5 TO LEAVE INDIGENT OUT AND DEFINE UNINSURED CAREFULLY  
6 OVER THE NEXT PERIOD OF TIME TO MAKE SURE IT COVERS THE  
7 PEOPLE WE WANT TO BE COVERED.

8 MR. GOLDBERG: I'M VERY SUPPORTIVE OF THAT.

9 DR. PENHOET: WITH THAT, I THINK WE DID CALL  
10 THE QUESTION THOUGH. THERE WAS A MOTION TO INCLUDE THE  
11 WORD "INDIGENT." YOU WANT TO WITHDRAW YOUR MOTION?

12 MR. GOLDBERG: I'LL EITHER AMEND THE MOTION  
13 OR ELIMINATE THE MOTION.

14 DR. PENHOET: YOU CAN WITHDRAW YOUR MOTION.

15 MR. GOLDBERG: I'D LIKE TO WITHDRAW MY  
16 MOTION.

17 DR. PENHOET: IS THE SECOND AGREEABLE TO  
18 WITHDRAWING THE MOTION TO INCLUDE THE WORD "INDIGENT"?

19 DR. PIZZO: SAY THAT AGAIN.

20 CHAIRMAN KLEIN: THE QUESTION WAS, DR. PIZZO,  
21 GIVEN THE DISCUSSION, GIVEN WE'RE GOING TO HAVE AN  
22 OPPORTUNITY BEFORE WE GO OUT WITH THE OAL NOTICE --

23 DR. PIZZO: I WITHDRAW.

24 DR. PENHOET: THE MAKERS OF THE MOTION HAVE  
25 WITHDRAWN THE MOTION. IS THERE ANYBODY WHO WANTS TO



1 MAKE THE MOTION AGAIN? IF NOT, THEN WE HAVE APPROVED  
2 THIS SECTION. CLARIFICATION, INDIGENT IS NOW REMOVED,  
3 WE'VE ADDED THE WORD "ONLY" IN RESPONSE TO WENDY  
4 STREITZ' SUGGESTION. I THINK WE HAVE VOTED ON THIS.  
5 WE HAVE APPROVED IT, SO WE'LL MOVE ON.

6 DR. REED: IF WE COULD GET THE PENULTIMATE  
7 SENTENCE IN WHAT WE JUST APPROVED, AND I'M ONE OF THE  
8 PEOPLE THAT VOTED YES FOR IT, I THINK THERE'S SOMETHING  
9 WRONG WITH THE WORDING THERE.

10 DR. PENHOET: PLEASE BE SPECIFIC. WHAT IS IT  
11 THAT YOU DON'T LIKE?

12 DR. REED: NO. 4. IF WE GET THIS PHRASE  
13 "WILL BE PURCHASED IN CALIFORNIA BY PUBLIC FUNDS THE  
14 THERAPEUTICS AND DIAGNOSTICS AT A COST NOT TO EXCEED,"  
15 THAT'S OKAY. BUT THE PART BEFORE THAT, THERE WAS  
16 SOMETHING THAT LOOKED LIKE IT WAS OUT OF WHACK. IN  
17 ADDITION, SUCH LICENSEES WILL AGREE TO PROVIDE THE  
18 PATIENTS THOSE THERAPIES AND DIAGNOSTICS WILL BE  
19 PURCHASED. THERE'S SOMETHING MISSING BEFORE THAT WILL  
20 BE. I THINK WE LOST A WORD OR SOMETHING.

21 DR. PENHOET: LICENSEES WILL AGREE TO PROVIDE  
22 THE PATIENTS WHOSE THERAPIES AND DIAGNOSTICS WILL BE  
23 PURCHASED IN CALIFORNIA BY PUBLIC FUNDS THE THERAPIES  
24 AND DIAGNOSTICS AT A COST NOT TO EXCEED THE FEDERAL  
25 MEDICAID PRICE. I THINK IT SAYS WHAT WE WANT TO SAY.

1 DR. REED: MAYBE NEED A COMMA OR SOMETHING.  
2 I DON'T KNOW.

3 DR. PENHOET: OKAY. MOVING ALONG.  
4 REQUIREMENTS FOR CIRM-FUNDED PATENTED INVENTIONS. THIS  
5 IS BASICALLY DUE DILIGENCE CLAUSES, THAT THEY COME UP  
6 WITH PLANS FOR -- ESSENTIALLY PLANS FOR HOW THEY'RE  
7 GOING TO COMMERCIALIZE THE TECHNOLOGY, PLANS TO MAKE  
8 THE TECHNOLOGIES REASONABLY ACCESSIBLE TO THE PUBLIC  
9 FOR RESEARCH PURPOSES, ETC.

10 THE NEXT SECTION IS REQUIREMENTS TO ENABLE  
11 RESEARCH EXEMPTIONS FOR CIRM-FUNDED PATENTED  
12 INVENTIONS. THIS IS A DIFFERENT SUBJECT. SO DO ANY OF  
13 YOU HAVE ANY COMMENT ON (H)(D)(5)?

14 CAN I HAVE A MOTION FOR APPROVAL OF THIS  
15 SECTION? I'M SORRY.

16 DR. PRIETO: JUST A QUESTION. THE LETTER WE  
17 GOT FROM THE SALK INSTITUTE, AND I GUESS THIS IS A  
18 LEGAL POINT, RECOMMENDED USE OF THE WORD "RESEARCH  
19 EXCLUSION" VERSUS RESEARCH EXEMPTION. I'M NOT SURE I  
20 UNDERSTAND WHAT THE DISTINCTION IS OR WHY THAT MATTERS.

21 DR. PENHOET: I THINK IT'S A FINE POINT WHICH  
22 I, FRANKLY, DIDN'T UNDERSTAND MYSELF. IF SOMEONE CAN  
23 EXPLAIN THE DIFFERENCE BETWEEN AN EXEMPTION AND AN  
24 EXCLUSION. ANYBODY FROM THE SALK HERE TODAY? NO. IN  
25 FACT, I THINK THE APPLICATION OF THESE TERMS HAVE TO BE

1 THE SAME.

2 MR. GOSWAMI: JOYDEEP GOSWAMI HERE AGAIN.

3 JUST PURSUANT TO THE PREVIOUS DISCUSSION, THAT MOST OF  
4 THE MONITORING REQUIREMENTS SHALL ONLY BE FOR EXCLUSIVE  
5 LICENSES, IS THERE GOING TO BE A CHANGE IN THIS CLAUSE  
6 AS WELL?

7 DR. PENHOET: YES, TO CONFORM, FOR EXCLUSIVE  
8 LICENSES, THAT'S CORRECT.

9 CHAIRMAN KLEIN: DR. PENHOET, I DON'T KNOW IF  
10 THE TRANSCRIPTIONIST GOT YOUR COMMENT. YOU SAID, YES,  
11 IT IS FOR EXCLUSIVE?

12 DR. PENHOET: YES, IT WILL CONFORM TO THE  
13 REQUIREMENT FOR DILIGENCE, ETC., FOR EXCLUSIVE  
14 LICENSES.

15 CHAIRMAN KLEIN: THANK YOU.

16 DR. PENHOET: OKAY. SO WITH THAT CHANGE, CAN  
17 WE HAVE A MOTION FOR APPROVAL OF (D)(5)?

18 DR. WRIGHT: SO MOVED.

19 DR. PENHOET: IS THERE A SECOND?

20 DR. PRIETO: SECOND.

21 DR. PENHOET: ALL IN FAVOR. MOTION CARRIED.

22 SHARING REQUIREMENTS TO ENABLE RESEARCH  
23 EXEMPTION FOR CIRM-FUNDED PATENTED INVENTIONS. GRANTEE  
24 ORGANIZATIONS AGREE THAT CALIFORNIA RESEARCH  
25 INSTITUTIONS MAY USE THEIR CIRM-FUNDED PATENTED

1 INVENTIONS FOR RESEARCH PURPOSES AT NO COST. GRANTEE  
2 ORGANIZATIONS SHALL, AND THEN WE'VE ADDED NEW LANGUAGE  
3 HERE, INSTEAD OF SAYING REQUIRE THE SAME AGREEMENT OF  
4 EACH OF THEIR LICENSEES, WE NOW SAY THAT ENSURE THAT  
5 SUCH USE IS PRESERVED IN THEIR LICENSES OF CIRM-FUNDED  
6 PATENTED INVENTIONS. SO THIS OBLIGATES NOT ONLY THE  
7 GRANTEES, BUT THEIR LICENSEES TO PROVIDE A FREE USE OF  
8 THE TECHNOLOGY FOR RESEARCH PURPOSES ONLY. THIS WAS AN  
9 AREA OF SOME DEBATE AND CONCERN.

10 DR. BRYANT: SO I WAS JUST WONDERING WHY YOU  
11 CHANGED THE LANGUAGE FROM BAYH-DOLE TO INSTEAD OF  
12 RESEARCH AND EDUCATION. WE'RE ALSO DOING EDUCATION.  
13 WE HAVE TRAINING GRANTS AND SO FORTH. SO BECAUSE OF  
14 THE MIXED FUNDING ISSUES LATER ON, IT MIGHT BE EASIER  
15 JUST TO KEEP THE SAME LANGUAGE.

16 DR. PENHOET: WHICH LANGUAGE SPECIFICALLY ARE  
17 YOU REFERRING TO?

18 DR. BRYANT: FOR RESEARCH AND EDUCATION  
19 PURPOSES. THAT WOULD BE CONSISTENT WITH BAYH-DOLE.

20 DR. PENHOET: TO ENABLE A RESEARCH AND  
21 EDUCATION EXEMPTION, IS THAT WHAT YOU MEAN?

22 DR. BRYANT: NO.

23 DR. PENHOET: WHERE ARE YOU?

24 DR. BRYANT: NO. 1, PATENTED INVENTIONS.

25 DR. PENHOET: YOU WANT TO SAY THAT AGREE

1 CALIFORNIA RESEARCH AND EDUCATION INSTITUTIONS?

2 DR. BRYANT: WAIT A MINUTE. I'M IN THE WRONG  
3 PLACE. I WITHDRAW MY COMMENT.

4 DR. PENHOET: THERE WAS SOME CONCERN ABOUT  
5 FORCING LICENSEES TO PROVIDE THIS RESEARCH EXEMPTION  
6 ARTICULATED BY SOME. HOWEVER, WE EXPECT, FIRST OF ALL,  
7 THAT THERE WILL BE RECIPROCITY BETWEEN THE PRIVATE  
8 SECTOR AND THE PUBLIC SECTOR IN THIS REGARD. WE HAVE  
9 HAD AN OFFER TO US BY GERON CORPORATION TO MAKE THEIR  
10 TECHNOLOGY AVAILABLE ON A RESEARCH BASIS TO THE  
11 COMMUNITY. AND SO WE BELIEVE, BASED ON THAT OVERTURE  
12 FROM THEM, THAT THE COMPANIES THAT LICENSE TECHNOLOGY  
13 WILL BE WILLING TO ENSURE THAT IT'S IN THE SAME POOL AS  
14 OTHERS. SO THAT'S THE BACKGROUND OF THIS.

15 ANY FURTHER COMMENT ON THIS PARTICULAR  
16 SECTION?

17 CHAIRMAN KLEIN: JUST CERTAINLY INTENDED THAT  
18 AT NO COST MEANS OTHER THAN THE COST OF REIMBURSING THE  
19 PRODUCTION OF THE BIOMEDICAL MATERIALS.

20 DR. PENHOET: THAT'S COVERED IN A DIFFERENT  
21 SECTION. THIS IS ONLY INTELLECTUAL PROPERTY. THERE'S  
22 NO COST ASSOCIATED.

23 CHAIRMAN KLEIN: THANK YOU FOR THE  
24 CLARIFICATION.

25 DR. PENHOET: COULD I HAVE A MOTION TO

1 APPROVE THIS SECTION?

2 CHAIRMAN KLEIN: MOTION.

3 MR. GOSWAMI: JOYDEEP GOSWAMI HERE AGAIN FROM  
4 INVITROGEN. COUPLE OF QUESTIONS HERE. FIRST, IS  
5 THERE -- HAS THE TERM "CALIFORNIA RESEARCH INSTITUTION"  
6 BEEN DEFINED ANYWHERE? SO WHAT DOES THE COMMITTEE SEE  
7 THAT AS? IS IT JUST ANY ORGANIZATION THAT HAS A  
8 RESEARCH BASE, HOWEVER SMALL, IN CALIFORNIA, INCLUDING  
9 PRIVATE AND FOR-PROFIT OR NONPROFIT? SO THEN IF THAT'S  
10 TRUE, I GUESS MY CONCERN HERE IS THEN HOW DOES THIS  
11 HELP POTENTIAL LICENSEES? OR HOW DOES IT PROTECT THE  
12 LICENSEES? IF ANY INVENTION THAT CAN BE LICENSED IS  
13 NOW AVAILABLE TO ANYBODY IN CALIFORNIA AT NO COST, WHY  
14 WOULD ONE WANT TO LICENSE THE TECHNOLOGY THAT ANYONE IN  
15 CALIFORNIA CAN USE? WHAT'S THE PRICE? WHAT'S THE  
16 MARKET PRICE ON THAT?

17 DR. PENHOET: THEY CAN USE IT FOR RESEARCH  
18 PURPOSES. THEY CAN'T USE IT FOR COMMERCIAL PURPOSES.  
19 IT SAYS RESEARCH PURPOSES.

20 MR. GOSWAMI: THAT'S TRUE, BUT FOR THE  
21 RESEARCH TOOLS INDUSTRY, THAT'S A DEATH KNELL. THIS  
22 ISSUE HAS BEEN DEBATED AT A NATIONAL LEVEL LAST YEAR  
23 WHERE SUCH A RESEARCH USE EXEMPTION WAS CONTEMPLATED,  
24 BY THE WAY, BY SOME OF THE GROUPS THERE. AND EVEN THE  
25 NATIONAL ACADEMY OF SCIENCES CAME OUT VERY SPECIFICALLY

1     AGAINST THIS, WARNING THAT RESEARCH -- A BROAD RESEARCH  
2     USE EXEMPTION POLICY ACTUALLY IS NOT IN THE INTEREST OF  
3     RESEARCH TOOLS.

4             SO MY CONCERN AND OUR ORGANIZATION'S CONCERN,  
5     AND I THINK BIOCOM AND OTHERS HAVE ALSO SPOKEN OUT  
6     AGAINST THIS, IS THAT THIS TAKES AWAY INCENTIVE FOR  
7     LICENSING. FOR ALL THE PREVIOUS DISCUSSIONS, IT TAKES  
8     AWAY THE INCENTIVE THAT THERE IS IN THE TOOLS INDUSTRY  
9     TO QUICKLY DISSEMINATE THE INVENTIONS BACK TO THE  
10    RESEARCH COMMUNITY.

11            DR. PENHOET: AGAIN, IT'S A REQUIREMENT ONLY  
12    THAT THEY MAKE SUCH AVAILABLE TO THE CIRM-FUNDED  
13    INSTITUTIONS, NOT TO THE WHOLE WORLD, BUT YOUR POINT IS  
14    WELL TAKEN.

15            ANY OTHER PUBLIC COMMENT?

16            MR. SIMPSON: JOHN SIMPSON FROM THE  
17    FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. THIS  
18    SEEMS TO ME TO BE AN ESSENTIAL POINT OF YOUR PREMISE OF  
19    TRYING TO SHARE RESEARCH AS WIDELY AS POSSIBLE. AND IF  
20    YOU DID NOT ALLOW THIS, YOU COULD HAVE A SITUATION  
21    WHERE ESSENTIALLY THE TAXPAYERS WOULD BE FORCED TO BE  
22    PAYING TWICE FOR THINGS THAT THEY'VE ALREADY PAID FOR  
23    ONCE TO DEVELOP. SO YOU WANT ANY CIRM RESEARCHER TO BE  
24    ABLE TO BENEFIT FROM RESEARCH THAT'S BEEN DONE BY CIRM  
25    FUNDS. IT'S JUST ONLY LOGICAL.

1 DR. PENHOET: IT DOES FALL SHORT OF SOME  
2 PROPOSALS WE HAD, WHICH WAS CREATING PATENT POOLS AND A  
3 COMMONS, ETC., AND WE DECIDED THIS WAS, IN OUR  
4 COMMITTEE, A REASONABLE MIDDLE GROUND BETWEEN THE  
5 VARIOUS PROPOSALS.

6 ANY OTHER COMMENT BY THE AUDIENCE OR BY THE  
7 BOARD? IF NOT, DO I HAVE A MOTION FOR APPROVAL OF THIS  
8 SECTION?

9 DR. FRIEDMAN: SO MOVED.

10 DR. PENHOET: DR. FRIEDMAN. IS THERE A  
11 SECOND?

12 DR. WRIGHT: SECOND.

13 DR. THAL: SECOND.

14 DR. PENHOET: ALL IN FAVOR. OPPOSED?

15 MOVE TO THE NEXT SECTION, REVENUE SHARING  
16 REQUIREMENTS. THIS HAS BEEN THE SUBJECT OF A LOT OF  
17 DEBATE AND DISCUSSION WITH VARIOUS PARTIES. AND THE  
18 PROPOSAL IN FRONT OF YOU IS THAT GRANTEE ORGANIZATIONS  
19 SHALL SHARE A FRACTION OF ANY, AND WE REMOVED THE  
20 ROYALTY TERM, SO IT'S ANY REVENUES IN ACCORDANCE WITH  
21 ESTABLISHED POLICIES.

22 AND SECOND OF ALL, THAT THE GRANT  
23 ORGANIZATIONS MAY RETAIN A THRESHOLD AMOUNT OF ITS  
24 SHARE OF ANY REVENUES RECEIVED UNDER A LICENSE  
25 AGREEMENT OR AGREEMENTS OF ANY CIRM-FUNDED PATENTED



1 INVENTIONS. THEREAFTER THE GRANTEE ORGANIZATION SHALL  
2 PAY 25 PERCENT OF ITS SHARE OF SUCH REVENUES TO THE  
3 STATE OF CALIFORNIA FOR DEPOSIT IN THE GENERAL FUND  
4 SUBJECT TO THE VIOLATION OF FEDERAL LAW. THE THRESHOLD  
5 AMOUNT IS 500,000. I THINK I DISCUSSED THAT EARLIER,  
6 MULTIPLIED BY THIS FRACTION, WHICH IS AN INFLATION  
7 ESCALATOR CLAUSE. ALL ITEMS, ETC. SO THIS IS, AGAIN,  
8 BEING RESPONSIVE TO A DEMAND FOR, I THINK, IN  
9 ANTICIPATION OF PROP 71 THAT THERE WOULD BE A DIRECT  
10 FINANCIAL REMUNERATION TO THE STATE FOR ITS \$3 BILLION  
11 INVESTMENT. THIS OBVIOUSLY DECREASES THE PORTION THAT  
12 THE UNIVERSITIES WOULD TAKE, BUT NOT THAT THE INVENTORS  
13 WOULD TAKE. AND SO THIS WAS THE COMPROMISE WE REACHED.  
14 I THINK IT SEEMED TO BE A REASONABLE COMPROMISE  
15 ACCEPTED BY MOST OF THE CONSTITUENTS WE TALKED ABOUT AS  
16 SUCH.

17 ANY COMMENT FROM THE BOARD ON THIS ONE?

18 DR. BRYANT: I WOULD SUGGEST THAT IT BE NET  
19 REVENUE, NOT GROSS REVENUES BECAUSE THERE'S NO WAY TO  
20 PREDICT AHEAD OF TIME HOW COSTLY THE PROSECUTION OF THE  
21 PATENTS ARE GOING TO BE, ESPECIALLY IN THIS AREA.

22 DR. PENHOET: ANY OTHER COMMENT?

23 DR. JENNINGS: POINT OF CLARIFICATION. BY  
24 REVENUES YOU INCLUDE THE SALE OF STOCK?

25 DR. PENHOET: YES.

1 DR. REED: I HAVE ONE. AND THAT'S ABOUT THE  
2 THRESHOLD. I THINK IN MOST CIRCUMSTANCES, BASED ON  
3 WHAT IT CURRENTLY COSTS TO PROSECUTE PATENTS, IT'S  
4 PROBABLY NOT UNREASONABLE, BUT I THINK WE SHOULD HAVE  
5 SUFFICIENT FLEXIBILITY TO RECOGNIZE THERE MAY BE CASES  
6 WHERE THE HALF-MILLION-DOLLAR EXCLUSION IS NOT  
7 ADEQUATE. THERE MAY BE CASES WHERE PATENTS FALL INTO  
8 INTERFERENCES OR OTHER SORTS OF ACTIONS THAT REQUIRE  
9 THE INSTITUTION TO DEFEND THEM. THOSE CAN BE VERY  
10 EXPENSIVE, AS YOU KNOW.

11 I WOULD SUGGEST WE -- I CAN POSE IT AS A  
12 MOTION, IF OTHERS FELT IT WAS APPROPRIATE, THAT WE ADD  
13 A SENTENCE THAT BASICALLY ALLOWS SOME FLEXIBILITY IN  
14 THERE. I MIGHT PROPOSE, FOR EXAMPLE, THAT WE TACK ON A  
15 SENTENCE AT THE END OF SECTION II THERE THAT SAYS  
16 SOMETHING TO THE EFFECT THAT IT IS RECOGNIZED, HOWEVER,  
17 THAT EXCEPTIONAL CASES MAY EXIST WHERE THE GRANTEE  
18 ORGANIZATION'S EXPENSES ASSOCIATED WITH MAINTAINING AND  
19 DEFENDING CIRM-FUNDED INTELLECTUAL PROPERTY MAY WARRANT  
20 A HIGHER THRESHOLD, WHICH WOULD BE NEGOTIATED BY THE  
21 CIRM AND GRANTEE ORGANIZATION.

22 DR. PENHOET: THAT'S A THOUGHT. ONE OTHER  
23 WAY TO ADDRESS THAT ISSUE WOULD BE TO ACCEPT SUE  
24 BRYANT'S PROPOSAL FOR NET REVENUES, NET REVENUES BEING  
25 DEFINED AS THE DIRECT COSTS ASSOCIATED WITH THE

1 PROSECUTION OF THE PATENT THAT'S SUBJECT TO THESE  
2 LICENSES, BUT NOT OTHER DIRECT COSTS.

3 WE DID HAVE A LOT OF DISCUSSION OF THIS IN  
4 OUR MEETING. I THINK THERE WAS A GENERAL VIEW THAT  
5 UNIVERSITIES EITHER GET THE 500,000 OR DIRECT COST, BUT  
6 NOT BOTH. IN THE CASE YOU TALKED ABOUT, IF NET  
7 REVENUES WAS DEFINED ON A NARROW BASIS, YOU COULD STILL  
8 KEEP THE \$500,000 IN PLACE, BUT THEN DEFINE NET  
9 REVENUES AS THOSE REVENUES IN EXCESS OF THE DIRECT  
10 COSTS OF THE PATENTING ACTIVITIES ASSOCIATED ON A  
11 PATENT SUBJECT TO THIS LICENSE. THAT WOULD BE ONE WAY  
12 TO DEAL WITH THIS.

13 DR. BRYANT: I WAS JUST GOING TO SAY THAT  
14 READING OVER THE LETTER THAT WE GOT FROM SENATOR ORTIZ,  
15 SHE ACTUALLY CALLS IT 25 PERCENT OF NET REVENUES OR NET  
16 ROYALTIES IN HER LETTER.

17 DR. PENHOET: IT'S WITHOUT A \$500,000  
18 THRESHOLD IN HER LETTER. AND THERE WAS -- I'M NOT SURE  
19 SHE KNOWS -- THERE ARE A LOT OF DEFINITIONS OF NET  
20 REVENUES THAT COULD BE OUT THERE.

21 MY OWN PERSONAL BELIEF IS THAT DR. REED'S  
22 PROPOSAL IS A SENSIBLE ONE, THAT WE COMBINE YOUR TWO,  
23 BUT WE DEFINE NET REVENUES NARROWLY AS DIRECT COSTS  
24 ASSOCIATED WITH THE PATENT SUBJECT TO THE LICENSE.

25 MS. SAMUELSON: QUESTION, AND MAYBE IT'S A

1 QUESTION FOR JAMES. IS THIS PURSUANT TO ANY SPECIFIC  
2 PROVISION OF PROP 71, OR IS THIS A PROPOSAL THAT  
3 PROVIDES LANGUAGE FOR THE FIRST TIME TO IMPLEMENT THE  
4 PERCEPTION OF AN OBLIGATION RELATED TO PROP 71, OR  
5 SOMETHING ELSE ENTIRELY?

6 MR. HARRISON: THERE IS A SPECIFIC PROVISION  
7 IN PROPOSITION 71 THAT REQUIRES YOU AS A BOARD TO ADOPT  
8 STANDARDS THAT REQUIRE ALL GRANTS AND LOAN AWARDS BE  
9 SUBJECT TO INTELLECTUAL PROPERTY AGREEMENTS THAT  
10 BALANCE THE OPPORTUNITY OF THE STATE OF CALIFORNIA TO  
11 BENEFIT FROM THE PATENTS, ROYALTIES, AND LICENSES THAT  
12 RESULT FROM BASIC RESEARCH, THERAPY DEVELOPMENT, AND  
13 CLINICAL TRIALS WITH THE NEED TO ASSURE THAT ESSENTIAL  
14 MEDICAL RESEARCH IS NOT UNREASONABLY HINDERED BY THE  
15 INTELLECTUAL PROPERTY AGREEMENTS.

16 SO THIS PROPOSAL IS INTENDED TO ADDRESS THE  
17 BALANCING REQUIREMENT SET FORTH IN THE ACT ITSELF.

18 MS. SAMUELSON: AND I GUESS MY QUESTION FOR  
19 THE TASK FORCE IS WHAT EXPLORATION DID YOU DO TO  
20 DETERMINE THAT THIS WAS -- THAT MET THAT BALANCING  
21 TEST? BECAUSE THIS APPEARS TO ME TO BE ANOTHER BURDEN  
22 ON THE DEVELOPMENT OF BREAKTHROUGH THERAPIES, OF WHICH  
23 THERE ARE LOTS OF DISINCENTIVES ALREADY, CERTAINLY IN  
24 PARKINSON'S, AND I'M CONCERNED ABOUT IT. AND WE HEARD  
25 THIS MORNING THE COST JUST OF DIABETES TO THE STATE AND

1 THE COUNTRY AND SPECIFICALLY, THEN, TO THE STATE IN  
2 LOST TAX REVENUES AND SO ON. IF WE COULD CURE DIABETES  
3 QUICKLY, LET'S SAY, EVEN SAVED JUST A YEAR OR TWO OF  
4 THAT LOST REVENUE, THAT WOULD PROBABLY GREATLY EXCEED  
5 THE REVENUE FLOW FROM ROYALTIES, WOULD IT NOT? SO  
6 LET'S NOT BE POUND FOOLISH.

7 DR. PENHOET: I MIGHT POINT OUT, JOAN, THIS  
8 DOES NOT DIRECTLY AFFECT THE LICENSE TERMS THEMSELVES  
9 OF ANY LICENSEE, SO THE COMMERCIAL ORGANIZATION IS NOT  
10 PARTICIPATING IN THIS. THIS IS 25 PERCENT OF WHATEVER  
11 REVENUE THE UNIVERSITY GETS OR OTHER NONPROFIT  
12 INSTITUTIONS AS A RESULT OF THEIR LICENSING ACTIVITY.  
13 THIS IS NOT A REACH-THROUGH ROYALTY TO THE LICENSEE.  
14 THIS IS JUST HOW THE UNIVERSITY OR OTHER NONPROFIT  
15 INSTITUTION SHARES ITS REVENUES THAT IT GETS FROM  
16 LICENSEES WITH THE STATE. BUT IT DOESN'T SPEAK AT ALL  
17 TO WHAT THE TERMS OF THE LICENSE ITSELF MIGHT BE.

18 MS. SAMUELSON: SO THIS ISN'T A BURDEN ON THE  
19 FOR-PROFIT RESEARCH INDUSTRY?

20 DR. PENHOET: THAT'S NOT THE INTENT.

21 GRANTEE ORGANIZATIONS SHALL SHARE A FRACTION  
22 OF ANY NET REVENUES WITH THE INVENTORS IN ACCORDANCE  
23 WITH THEIR ESTABLISHED POLICY. NET REVENUES ARE  
24 DEFINED AS GROSS REVENUES MINUS DIRECT COSTS INCURRED  
25 IN THE GENERATION AND PROTECTION OF THE PATENTS FROM

1 WHICH THE REVENUES ARE RECEIVED.

2 IS THAT REASONABLE LANGUAGE, DR. BRYANT?

3 OKAY. DO I HAVE A MOTION FOR APPROVAL OF THIS SECTION  
4 AS AMENDED? EXCUSE ME. DR. PIZZO.

5 DR. PIZZO: THAT'S ALL RIGHT.

6 DR. PENHOET: IS THERE PUBLIC COMMENT?

7 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR  
8 TAXPAYER AND CONSUMER RIGHTS. IT SEEMS TO ME THAT THIS  
9 CLEARLY HAS TO BE NET REVENUES. AND THE WAY THEY'RE  
10 DEFINED IS FINE. THE ONLY THING IS THAT ONCE YOU HAVE  
11 NET REVENUES, I WOULD THINK THAT THE \$500,000 THRESHOLD  
12 IS EXCESSIVE. \$100,000 IS A LOT OF THE MONEY IN MY  
13 BOOK, AND THAT'S WHERE I WOULD PUT THE THRESHOLD,  
14 PARTICULARLY ONCE YOU ACKNOWLEDGE NET REVENUES AND THEY  
15 CAN HAVE THE COST BACK OF DEFENDING AND CLAIMING THE  
16 PATENT.

17 MS. STREITZ: WHAT I WAS FIRST GOING TO SAY,  
18 AND I HAVE ANOTHER COMMENT NOW, THE NET REVENUE  
19 DEFINITION SHOULD BE GROSS LESS DIRECT COSTS INCURRED  
20 AND LESS THE INVENTOR'S SHARE BECAUSE THAT'S CONSISTENT  
21 WITH THE REST OF THIS PROVISION, IS THAT WE PAID OUR  
22 INVENTORS AND THEN WE SHARE OUT OF THAT. SO THAT'S A  
23 CLARIFICATION.

24 AND ARE WE JUST TALKING ABOUT SECTION I RIGHT  
25 NOW?

1 DR. PENHOET: ARE WE TALKING ABOUT WHAT?

2 MS. STREITZ: LITTLE 1 OR (1) AND (2).

3 DR. PENHOET: FEEL FREE TO COMMENT ON EITHER  
4 ONE OF THEM.

5 MS. STREITZ: THAT CONCEPT OF AFTER PAYMENT  
6 TO INVENTORS NEEDS TO BE PICKED UP IN TWO PLACES IN (2)  
7 AS WELL. SO THE FIRST WOULD BE THE GRANTEE  
8 ORGANIZATION MAY RETAIN A THRESHOLD AMOUNT OF ITS SHARE  
9 AFTER PAYMENT TO INVENTORS. AND THE SECOND IS IN THE  
10 FOLLOWING SENTENCE, IT SAYS THEREAFTER THE GRANTEE  
11 ORGANIZATION SHALL PAY 25 PERCENT OF ITS SHARE, AND,  
12 AGAIN, WE WOULD SAY AFTER PAYMENT TO INVENTORS JUST TO  
13 MAKE SURE THAT CARRIES THROUGH, JUST TO BE CONSISTENT.

14 AS FOR THE \$100,000 THRESHOLD, THE ONE THING  
15 I WOULD JUST PUT ON THE TABLE TO CONSIDER IS IN THE  
16 UNSUCCESSFUL -- ONE OF THE CONCEPTS HERE IS THAT WE'RE  
17 TALKING ABOUT A SUCCESSFUL INVENTION, IT'S EARNED  
18 INCOME, AND WE'RE SHARING THE INCOME. AND THERE ARE A  
19 NUMBER OF UNSUCCESSFUL ONES FOR EVERY ONE THAT'S  
20 SUCCESSFUL. SOME OF THE UNSUCCESSFUL ONES, THE COSTS  
21 CAN RUN UP PRETTY DRAMATICALLY, INCLUDING OVER THE  
22 \$100,000, ESPECIALLY IF WE HAVE TO DEFEND THEM IN SOME  
23 MANNER.

24 MS. KU: KATHY KU, STANFORD. I WOULD LIKE TO  
25 REITERATE WENDY'S COMMENTS. I ALSO FEEL LIKE THIS IS A

1     GOOD POLICY.  WE HAVE NO PROBLEM SHARING, BUT AS  
2     DIRECTOR, I'M REALLY CONCERNED ABOUT PRECEDENTS AND  
3     FAIRNESS TO OTHER SPONSORS.  SO I WOULD LIKE TO PROPOSE  
4     THAT THE STATE SHARE IN SOME OF THE RISK.

5             I WANT TO SHARE WITH YOU SOME OF THE NUMBERS  
6     ONLY BECAUSE I THINK WE'RE FOCUSED RIGHT NOW ON THE  
7     WINNERS, BUT THERE'S SO MANY MORE LOSERS THAT ARE GOING  
8     TO HAPPEN.

9             THE RULE OF THUMB IN OUR BUSINESS IS THAT  
10    THERE'S ABOUT ONE INVENTION OUT OF EVERY \$2 MILLION IN  
11    RESEARCH FUNDING.  SO PRESUMING THERE'S \$3 BILLION IN  
12    RESEARCH FUNDING, WHICH IS, I THINK, ON THE GENEROUS  
13    SIDE, WE WOULD EXPECT ABOUT 1500 INVENTIONS.  
14    STANFORD'S EXPERIENCE IS THAT WE FILE ON ABOUT 50  
15    PERCENT OF THAT, SO THAT'S 750 INVENTIONS, AND WE ONLY  
16    LICENSE HALF OF THOSE.  SO THAT MEANS, ONE, 21  
17    INVENTIONS MIGHT MAKE THIS \$500,000 THRESHOLD, BUT IT  
18    ALSO MEANS THAT ABOUT 375 INVENTIONS WE WILL HAVE FILED  
19    ON, SPENT A LOT OF MONEY, BUT NOT BEEN ABLE TO LICENSE.  
20    AND THOSE OTHER ONES THAT WE'VE BEEN ABLE TO LICENSE,  
21    THE NON-21, THEY'RE JUST GOING TO BE MINOR MONEY, AND  
22    WE MAY OR MAY NOT BREAK EVEN.

23            SO WHAT WE'RE LOOKING AT AT A MINIMUM IS  
24    SOMETHING LIKE \$6 MILLION IN PATENT EXPENSES.  I FEEL  
25    THAT THE RESEARCH INSTITUTIONS WHO ARE GOING TO HAVE TO



1 PUT THIS UP AND SHARE REVENUES WITH THE STATE WOULD BE  
2 MORE INCENTIVIZED TO FILE IF THE STATE WOULD ALSO SHARE  
3 IN THE RISK PROPORTIONATELY. SO IF WE'RE GOING TO GIVE  
4 THE STATE 25 PERCENT OF THE BENEFIT, I WOULD LIKE TO  
5 SEE THE STATE PAY FOR ABOUT 25 PERCENT OF THE PATENT  
6 EXPENSES.

7 I REALIZE THAT CIRM DOESN'T HAVE A BUDGET FOR  
8 THIS, SO I WOULD PROPOSE THAT CIRM OR THE STATE WOULD  
9 PAY FOR THIS THROUGH THE INCOME THAT WE WOULD PAY TO  
10 THE STATE SO THAT WE COULD SUBTRACT OFF SOME OF THE  
11 EXPENSES FROM THE INCOME. AT THE END OF THE DAY, WE  
12 HAVE AGREEMENTS WITH THE VETERANS ASSOCIATION, VETERANS  
13 ADMINISTRATION, THE VA, AND HHMI, HOWARD HUGHES MEDICAL  
14 INSTITUTE, AND THEY ALSO PAY FOR PART OF THE PATENT  
15 EXPENSES EVEN THOUGH WE DO SHARE ROYALTIES WITH THEM.  
16 SO I THINK FROM A FAIRNESS STANDPOINT, IT WOULD BE MOST  
17 FAIR IF THE STATE WOULD ALSO PAY FOR PART OF THE  
18 EXPENSES. THANK YOU.

19 MR. REED: THE 25-PERCENT SOLUTION SEEMS LIKE  
20 A REASONABLE COMPROMISE. I WOULD PREFER THAT IT DIDN'T  
21 EXIST AT ALL, BUT I ALSO DO NOT WANT ANYTHING THAT CAN  
22 GIVE THE OPPOSITION AN EXCUSE TO SUE US OR TO COME UP  
23 WITH LITIGATION TO BLOCK US IN ANY WAY, SO I THINK IT'S  
24 A REASONABLE COMPROMISE, SOMETHING TO BE PUT UP WITH.

25 DR. PENHOET: THANK YOU FOR YOUR COMMENTS.

1 KATHY, IN RESPONSE TO YOUR COMMENT, I BELIEVE  
2 THAT WE PUT THE 500 K FORWARD AS AN AMOUNT OF MONEY,  
3 THE THRESHOLD, TO HELP YOU DEFER THE COST OF THE  
4 NONPERFORMING PATENTS RATHER THAN THE DIRECT COSTS. I  
5 DON'T BELIEVE THERE'S ANY PROVISION ANYWHERE FOR US TO  
6 PAY FOR PATENT EXPENSES FOR GRANTEES. IT'S ONE OF THE  
7 REASONS WE USE FOR THE LOGIC BEHIND TRANSFERRING  
8 OWNERSHIP TO THE GRANTEES IN THE FIRST PLACE IS WE  
9 COULDN'T AFFORD TO PURSUE THIS OURSELVES.

10 MS. KU: UNFORTUNATELY THE 500,000 DOESN'T  
11 HELP US AT ALL BECAUSE IT'S FOR ONE INVENTION. THE  
12 INVENTOR AND SCHOOL AND DEPARTMENT FOR THAT PARTICULAR  
13 WINNER INVENTION ISN'T GOING TO HELP THE LOSERS.

14 DR. PENHOET: I THINK WE PARTIALLY ADDRESSED  
15 THAT HERE WITH THE NET REVENUES. AND WHAT WE HEARD WAS  
16 THE AVERAGE COST FOR YOUR PATENT PORTFOLIO IS NOT  
17 500,000. IT'S SIGNIFICANTLY LESS. ANYWAY, THAT'S HOW  
18 WE TRIED TO ADDRESS THAT ISSUE, BUT WE CAN REVISIT THE  
19 ISSUE HERE.

20 DR. PIZZO: JUST AS A FOLLOW-UP TO KATHY KU'S  
21 COMMENT, BUT PERHAPS MORE GENERICALLY, AND I THINK THIS  
22 DEALS WITH THE WAY WE COMMUNICATE ABOUT THIS TOPIC.  
23 BECAUSE SAYING THAT WE'RE GOING TO CONTRIBUTE 25  
24 PERCENT OF WHATEVER NET REVENUES ARE ACCRUED CAN IMPLY  
25 TO THE STATE THAT THERE'S GOING TO BE A LOT OF REVENUE

1     THAT'S GOING TO BE COMING INTO IT AS A CONSEQUENCE OF  
2     THE INVESTMENT THAT IS BEING MADE.  AND IN REALITY IT'S  
3     GOING TO BE A VERY RELATIVELY SMALL NUMBER, JUST BASED  
4     UPON THE EXPERIENCES CERTAINLY THAT WE HAVE AT  
5     STANFORD.

6             I THINK A LOT OF OUR DISCUSSION TODAY  
7     SURROUNDS THE EXPECTATION THAT IN SOME MANNER THE  
8     INVESTMENT THAT WE MAKE IS GOING TO IMPROVE HEALTHCARE  
9     OF OUR COMMUNITY, AND WE ALL HOPE THAT THAT'S GOING TO  
10    OCCUR, BUT IT'S NOT LIKELY THAT THAT'S GOING TO OCCUR  
11    AS A CONSEQUENCE OF THESE ROYALTIES.

12            AND SECONDLY, A GREAT PART OF OUR DISCUSSION  
13    TODAY IS REALLY A SURROGATE FOR DEFINING AN INEFFECTIVE  
14    HEALTHCARE SYSTEM THAT WE HAVE IN THIS STATE AND IN  
15    THIS NATION.  AND I THINK WE SHOULDN'T BE CONFUSED  
16    ABOUT THAT EITHER.  WE'RE SPENDING A LOT OF OUR TIME  
17    TRYING TO REPAIR A SYSTEM THAT IS BROKEN, AND I THINK  
18    THE WAY WE COMMUNICATE ABOUT THIS IS GOING TO BE REALLY  
19    IMPORTANT SO THAT WE DON'T HAVE ANOTHER SET OF  
20    EXPECTATIONS THAT THERE ARE GOING TO BE LARGE DOLLARS  
21    COMING FROM THIS THAT'S GOING TO REPAIR A SYSTEM THAT'S  
22    HIGHLY DEFECTIVE.

23            DR. PENHOET:  ANY COMMENTS FROM THE BOARD ON  
24    THIS SECTION AS NOW WRITTEN?

25            DR. LOVE:  I JUST WANTED TO POINT OUT I THINK

1 THE WAY IT WAS WRITTEN ORIGINALLY, WE WERE ONLY  
2 INCLUDING SHARING 25 PERCENT OF THE ROYALTIES. AND I  
3 THINK THE WAY IT'S WRITTEN NOW, IT COULD BE INTERPRETED  
4 TO INCLUDE BOTH MILESTONE PAYMENTS AND ROYALTIES. AND  
5 THAT MAY BE WHAT WE WANT TO DO. I JUST WANT TO MAKE  
6 SURE THAT AT LEAST MY READ OF NOW INCLUDING MILESTONES  
7 IN THIS MAY HAVE BEEN INADVERTENTLY DONE.

8 DR. PENHOET: THE INTENT, AT LEAST ON MY  
9 PART, AND I THOUGHT IT'S UNDERSTOOD WHAT WE DID WAS TO  
10 INCLUDE ALL REVENUES BECAUSE IT WAS POINTED OUT TO US  
11 THAT THERE ARE MANY WAYS TO GET REMUNERATION FOR  
12 UNIVERSITIES. AND IF THEY ONLY HAVE TO PAY 25 PERCENT  
13 OF ROYALTIES, THEY CAN ASK FOR ALL THE MONEY IN OTHER  
14 FORMS OF REMUNERATION. AND WE ARE SITTING IN THE HOUSE  
15 THAT GOOGLE BUILT HERE ON THE STANFORD CAMPUS, WHICH IS  
16 ALL EQUITY. SO I THINK THE SENSE OF OUR GROUP WAS THAT  
17 IT WOULD INCLUDE ALL SOURCES OF REVENUE, WHETHER  
18 THEY'RE STOCK, CASH, MILESTONES, WHATEVER, THAT COME TO  
19 THE --

20 DR. LOVE: I'M FINE WITH IT. I JUST DON'T  
21 THINK IT WAS WRITTEN THAT WAY ORIGINALLY. IT  
22 ORIGINALLY SAID --

23 DR. PENHOET: WE HAVE TAKEN OUT THE WORD  
24 "ROYALTIES" IN RESPONSE TO NUMEROUS CONCERNS THAT IT  
25 WAS SUBJECT TO GAMING, FRANKLY.

1 ANY OTHER COMMENTS? CAN I ASK FOR A MOTION  
2 TO APPROVE THIS AS WRITTEN, INCLUDING THE RED AND  
3 DELETING THE GREEN?

4 MS. STREITZ: I HAVE ONE MORE COMMENT ON (2),  
5 BUT (2) SCROLLS OVER TO THE NEXT SLIDE, SO I FORGOT.  
6 WHERE WE TALK ABOUT UNLESS SUCH ACTION VIOLATES ANY  
7 FEDERAL LAW, I THINK WHAT WE ARE REFERRING TO THERE IS  
8 BAYH-DOLE AND THE BAYH-DOLE REQUIREMENT THAT INCOME BE  
9 USED, AFTER RECOVERING EXPENSES AND PAYING INVENTORS,  
10 INCOME CAN BE USED FOR RESEARCH AND EDUCATION. AND IT  
11 JUST MAY BE HELPFUL SAY SO. MAYBE TO SAY ANY VIOLATION  
12 OF FEDERAL LAW SUCH AS THE REQUIREMENTS OF 35 UCS 202  
13 (C)(7)(C), WHICH IS THE SPECIFIC REQUIREMENT.

14 DR. PENHOET: WELL, WE'RE NOT SURE WHAT  
15 FEDERAL LAWS WILL COME IN THE FUTURE, SO WE LEFT IT AS  
16 FEDERAL LAWS GENERALLY.

17 IS THERE A MOTION TO APPROVE THIS?

18 DR. PIZZO: SO MOVED.

19 MR. SHEEHY: SO MOVED.

20 MR. GOLDBERG: SECOND.

21 DR. PENHOET: SECONDED BY GOLDBERG. ANY  
22 FURTHER DISCUSSION? ALL IN FAVOR. OPPOSED? THANK  
23 YOU.

24 WE'RE GETTING NEAR THE END, FOLKS. THIS IS A  
25 CONTINUATION. FUNDING SOURCES ARE, IN ADDITION TO

1 CIRM, THEN CIRM HAS A RIGHT ONLY TO A PROPORTIONAL PART  
2 THAT THEY FUNDED. AND GRANTEES SHALL APPLY THE  
3 GRANTEE'S ORGANIZATION'S SHARE OF ANY ROYALTIES, AND  
4 PERHAPS TO MAKE THIS CONSISTENT, WE NOW NEED TO SAY  
5 REVENUES EARNED AS A RESULT OF THESE PATENTED  
6 INVENTIONS FOR THE SUPPORT OF SCIENTIFIC RESEARCH AND  
7 EDUCATION.

8 SO WOULD YOU CHANGE THE WORD "ROYALTIES" TO  
9 "REVENUES." WITH THAT CHANGE, DO I HAVE A MOTION FOR  
10 APPROVAL OF THIS SECTION?

11 DR. REED: SO MOVED.

12 DR. PENHOET: DR. PIZZO, WOULD YOU LIKE TO  
13 MOVE APPROVAL OF THIS SECTION?

14 DR. PIZZO: YES.

15 DR. GOLDBERG: SECOND.

16 DR. PENHOET: SECONDED BY GOLDBERG. ALL IN  
17 FAVOR. OPPOSED? THANK YOU.

18 PRESS REQUIREMENTS, THIS IS PROBABLY AN EASY  
19 ONE. ANY CONCERN ABOUT THE WAY THIS IS WORDED? PUBLIC  
20 COMMENT?

21 SO DO I HAVE A MOTION FOR APPROVAL?

22 MR. GOLDBERG: SO MOVED.

23 CHAIRMAN KLEIN: SECOND.

24 DR. PENHOET: MOVED GOLDBERG, SECONDED KLEIN.  
25 ALL IN FAVOR.

1                   MARCH-IN RIGHTS. THIS IS THE LAST SECTION.  
2           BASICALLY IT SAYS WE'VE TAKEN OUT THE NONEXCLUSIVE  
3           LICENSEE WORDING IN HERE TO CONFORM WITH WHAT WE SAID  
4           BEFORE. IN A NONEXCLUSIVE LICENSING SITUATION, THE  
5           MARKETPLACE SHOULD TAKE CARE, IF ONE LICENSEE IS NOT  
6           PERFORMING, ANOTHER LICENSEE IS FREE TO DO IT, AND WE  
7           CAN LICENSE SOMEBODY ELSE AT WILL. SO WE THOUGHT IT  
8           WAS PROBABLY AN UNNECESSARY COMPLICATION TO PUT IN NOT  
9           TO HAVE IT REFER TO NONEXCLUSIVE LICENSEES.

10                   EVERYTHING NOW REFERS TO EXCLUSIVE LICENSEE,  
11           AND IT SAYS THAT THE STATE, CIRM, HAS THE RIGHT TO  
12           MARCH IN IF THEY'VE NOT MADE RESPONSIBLE EFFORTS IN A  
13           REASONABLE TIME TO ACHIEVE PRACTICAL APPLICATION OF THE  
14           PATENTED INVENTION. TWO WORDS WHICH ARE SOFT, BUT  
15           NEVERTHELESS SUBJECT TO, I THINK, REASONABLE  
16           INTERPRETATION.

17                   SECOND OF ALL, THEY FAIL TO ADHERE TO THE  
18           AGREED-UPON PLAN FOR ACCESS TO RESULTANT THERAPIES AS  
19           DESCRIBED PREVIOUSLY.

20                   THIRD ONE IS TO MEET REQUIREMENTS FOR PUBLIC  
21           USE, AND THE REQUIREMENTS HAVE NOT BEEN SATISFIED BY  
22           THE GRANTEE ORGANIZATION OR ITS LICENSEE.

23                   AND THEN FINALLY, IT'S TO ALLEVIATE A PUBLIC  
24           HEALTH AND SAFETY NEED WHICH AREN'T REASONABLY  
25           SATISFIED BY THE ORGANIZATION OR ITS LICENSEE AND WHICH

1       NEEDS TO CONSTITUTE A PUBLIC HEALTH EMERGENCY.

2               THERE'S A CURE PERIOD ASSOCIATED WITH THIS ON  
3       THE NEXT SLIDE. YOU'LL BE THRILLED TO KNOW THIS IS THE  
4       LAST SLIDE. IT SAYS CIRM WILL GIVE TO THE GRANTEE OR  
5       LICENSEE NOTICE OF SUCH DETERMINATION; I.E., ABOVE, AND  
6       THE BASIS UPON WHICH IT WAS MADE. CIRM WILL NOT  
7       EXERCISE ITS RIGHTS DESCRIBED ABOVE IF THE GRANTEE OR  
8       LICENSEE TAKES DILIGENT ACTION PROMPTLY TO CURE THE  
9       DEFICIENCY AND SUCH DEFICIENCY IS CURED SOONER THAN ONE  
10      YEAR FROM THE RECEIPT OF NOTICE OR LONGER BY A PERIOD  
11      OF MUTUAL AGREEMENT. WITH RESPECT TO DEFICIENCY  
12      DESCRIBED IN 1.4 ABOVE, CIRM MAY EXERCISE SUCH RIGHT AT  
13      ANY TIME -- THAT'S A PUBLIC HEALTH EMERGENCY -- IN THE  
14      EVENT OF A PUBLIC HEALTH OR SAFETY EMERGENCY.

15              ANY COMMENT ON THESE MARCH-IN RIGHTS?  
16      THEY'RE SIMILAR IN NATURE TO THE FEDERAL GOVERNMENT  
17      MARCH-IN RIGHTS, BUT WE THINK IN SOME WAYS THEY GO  
18      BEYOND THAT.

19              MR. SHEEHY: THERE WAS A REQUEST FROM THE  
20      PUBLIC TO HAVE SOME LANGUAGE OFFERING THE OPTION TO  
21      CIRM TO DESIGNATE THE ATTORNEY GENERAL TO ENFORCE  
22      THESE.

23              DR. PENHOET: IN THE POLICY SECTION THERE IS  
24      A REFERENCE TO -- REFERENCE TO THE ATTORNEY GENERAL ON  
25      PAGE 2.



1 DR. MAXON: AT THE END OF THE FIRST  
2 PARAGRAPH.

3 DR. PENHOET: PAGE 2 OF THE ENTIRE DOCUMENT.

4 MR. SHEEHY: I HATE TO GO TO THE PUBLIC, BUT  
5 I JUST WANT TO MAKE SURE THAT SATISFIED THE PUBLIC  
6 CONCERN. I ASSUME THAT THE ATTORNEY GENERAL WOULD BE  
7 THE ENFORCING MECHANISM, BUT I JUST WANT TO MAKE SURE  
8 THAT THE PUBLIC CONCERN WAS ADDRESSED.

9 DR. PENHOET: THIS SECTION HAS THE FORCE OF  
10 LAW. I BELIEVE IT'S THE ATTORNEY GENERAL'S  
11 RESPONSIBILITY TO ENFORCE THE LAWS OF THE STATE OF  
12 CALIFORNIA. JAMES, I DON'T KNOW IF YOU WANT TO COMMENT  
13 ON THAT.

14 MR. HARRISON: THAT'S RIGHT. TO THE EXTENT  
15 THERE ARE VIOLATIONS OF THIS POLICY, THE AGENCY CAN  
16 REFER THOSE VIOLATIONS OR SUSPECTED VIOLATIONS TO THE  
17 ATTORNEY GENERAL FOR INVESTIGATION AND ENFORCEMENT. SO  
18 YOU HAVE THAT INHERENT RIGHT AS A STATE AGENCY.

19 DR. POMEROY: IS THERE SOMETHING IN ALL THOSE  
20 EXTRA PAGES THAT YOU HAVE THAT SAYS WHO DETERMINES WHAT  
21 A PUBLIC HEALTH OR SAFETY EMERGENCY IS? AND THIS  
22 ACTUALLY HAS COME UP IN REGARDS TO, SAY, HIV MEDICINES  
23 AND THAT SORT OF THING. HOW DO YOU DEFINE WHAT A  
24 PUBLIC HEALTH OR SAFETY EMERGENCY IS?

25 DR. PENHOET: I BELIEVE -- I'M NOT SURE. I'M

1 ON UNCERTAIN GROUND HERE. IF ANYBODY KNOWS MORE THAN I  
2 DO ABOUT THIS, PLEASE HELP. I BELIEVE THAT AN  
3 EMERGENCY WOULD BE CALLED BY THE DIRECTOR OF HHS FOR  
4 THE STATE OF CALIFORNIA. IN THIS CURRENT ENVIRONMENT  
5 KIM BELSHE, BUT I'M NOT POSITIVE THAT'S THE CASE.  
6 WE'LL CERTAINLY FOLLOW UP ON THAT DURING OUR 270-DAY  
7 PERIOD.

8 DR. KESSLER: JIM, WHAT'S THE STATUTORY  
9 AUTHORITY FOR THIS, FOR THE MARCH-IN RIGHTS?

10 MR. HARRISON: STATUTORY AUTHORITY FOR THE  
11 MARCH-IN RIGHTS IS THE AUTHORITY TO USE A BOARD TO  
12 ADOPT INTELLECTUAL PROPERTY POLICIES AND STANDARDS.

13 DR. KESSLER: ARE YOU CONVINCED THAT YOU HAVE  
14 THE -- CIRM HAS THE AUTHORITY BY STATUTE TO MARCH IN?

15 MR. HARRISON: YES. YOU AS A BOARD HAVE THE  
16 AUTHORITY TO ADOPT INTELLECTUAL PROPERTY STANDARDS  
17 THAT, AS I READ EARLIER, BALANCE THE RIGHT OF THE STATE  
18 OF CALIFORNIA TO BENEFIT FROM THE RESEARCH THAT IT  
19 FUNDS BALANCED AGAINST THE NEED NOT TO UNNECESSARILY  
20 IMPEDE RESEARCH. THAT'S A FAIRLY BROAD MANDATE.

21 DR. KESSLER: THAT'S NOT MY QUESTION. YOU  
22 HAVE THE AUTHORITY TO MARCH IN? WHERE DOES THAT  
23 AUTHORITY COME FROM?

24 MR. HARRISON: I BELIEVE THAT AUTHORITY IS  
25 WITHIN YOUR AUTHORITY TO DEVELOP INTELLECTUAL PROPERTY

1 POLICIES.

2 DR. KESSLER: I WOULD GET -- I'M NOT SURE.  
3 IT'S NOT OBVIOUS TO ME JUST BECAUSE YOU HAVE THE  
4 AUTHORITY TO REGULATE BROADLY, IT GIVES YOU CERTAIN  
5 AUTHORITIES TO CARRY OUT EVERY ACT YOU WANT TO CARRY  
6 OUT.

7 DR. PENHOET: THIS IS A NARROW REQUIREMENT  
8 ONLY TO CIRM-FUNDED PATENTED INVENTIONS AND THEIR  
9 LICENSEES. IT'S NOT A STATE -- STATE HAS NO RIGHT  
10 UNDER THIS TO MARCH IN ON ANY OTHER BASIS TO ANY OTHER  
11 AGREEMENT. IT'S ONLY FOR CIRM-FUNDED INVENTIONS.

12 DR. KESSLER: IF THERE'S A LEGAL OPINION, YOU  
13 HAVE A STATUTORY AUTHORITY TO MARCH IN, I JUST THINK  
14 BEFORE YOU ENACT REGULATIONS, WE HAVE THE SPECIFIC  
15 STATUTORY AUTHORITY OR WHETHER WE'RE EXCEEDING IT HERE.

16 MR. HARRISON: WE WILL INVESTIGATE THAT  
17 FURTHER. OF COURSE, ONE OF THE THINGS THE OFFICE OF  
18 ADMINISTRATIVE LAW DOES IS TO ASCERTAIN WHETHER, IN  
19 FACT, WE HAVE THAT AUTHORITY, SO WE WILL INVESTIGATE.

20 MR. SHESTACK: ISN'T IT A CONTRACTUAL  
21 AUTHORITY AS PART OF THE TERMS AND CONDITIONS  
22 ULTIMATELY THAT WILL BE PART OF ANYBODY RECEIVING  
23 MONIES FROM CIRM?

24 DR. PENHOET: WELL, WE CAN CLARIFY THIS LEGAL  
25 MATTER SUBSEQUENTLY IN THE 270-DAY NOTICE PERIOD.

1 DR. JENNINGS: AS A PRACTICAL MATTER, I THINK  
2 MOST GRANTING INSTITUTIONS, IF THEY GRANT AN EXCLUSIVE  
3 LICENSE, WILL PUT IN MARCH-IN RIGHTS IN THEIR  
4 AGREEMENT. THAT'S TYPICALLY WHAT WE DO AT CAL TECH.  
5 IF WE GRANT AN EXCLUSIVE LICENSE, WE WILL PUT IN  
6 MARCH-IN RIGHTS IN ORDER TO PROTECT OUR INVESTMENT.  
7 IT'S REDUNDANT.

8 MS. SAMUELSON: I HAVE A QUESTION ABOUT  
9 WORDING. IN SUBPARAGRAPH 1 IT TALKS ABOUT THE LICENSEE  
10 NOT HAVING MADE RESPONSIBLE EFFORTS IN A REASONABLE  
11 TIME TO ACHIEVE PRACTICAL APPLICATION. I'M COMPARING  
12 THAT TO BACK UNDER (H)(D)(5) WHERE IT TALKS ABOUT  
13 REMEDIES FOR FAILURE TO DEVELOP. IN THE EVENT THAT A  
14 LICENSEE IS UNABLE TO FULLY DEVELOP THE RIGHTS GRANTED.  
15 IF YOU ARE TRYING TO ACCOMPLISH THE SAME THING ROUGHLY,  
16 I'M LIKING THE LANGUAGE "THE REASONABLE EFFORTS IN A  
17 REASONABLE TIME" LANGUAGE. THIS OTHER ONE SOUNDS LIKE  
18 SOMETHING THAT YOU WOULD DETERMINE AFTER THE FACT, SAY,  
19 10, 20 YEARS AFTER A TECHNOLOGY HAS BEEN SITTING  
20 UNDEVELOPED IN THE HANDS OF ONE ENTITY.

21 AND THE POINT WOULD BE TO TRY TO KEEP PUSHING  
22 THE ENVELOPE. AND SO I WOULD THINK THAT IF THEY'RE  
23 TRYING TO ACCOMPLISH EQUIVALENT THINGS IN LANGUAGE,  
24 THAT THIS LANGUAGE WE'RE LOOKING AT NOW IS BETTER.

25 DR. PENHOET: IN RESPONSE TO THAT, I THOUGHT

1     YOU MIGHT MAKE A DIFFERENT COMMENT, JOAN.   THE MARCH-IN  
2     RIGHTS ARE SEEN AS THE MOST ONEROUS OF ALL POSSIBLE  
3     ADDITIONS TO ANY LICENSE AGREEMENT OR COMMUNITY OF  
4     LICENSORS.   SO I THINK THE FIRST LANGUAGE REFERRED TO  
5     THE OBLIGATION UNIVERSITIES HAD TO PURSUE DILIGENTLY  
6     THE DEVELOPMENT OF THESE PRODUCTS, ETC.   THIS IS A  
7     LEGAL RIGHT TO ACTUALLY GO IN OVER THE HEAD OF THE  
8     UNIVERSITY AND, THEREFORE, TO SOME DEGREE HAS CURE  
9     PERIODS, ETC., BECAUSE IN THIS CASE THERE WAS GREAT  
10    CONCERN ABOUT HAVING ANY MARCH-IN RIGHTS BEING  
11    SOMETHING THAT COMPANIES FEAR MOST OF ALL THINGS IN  
12    LICENSE AGREEMENTS.   AND I THINK OTHER PEOPLE AROUND  
13    THIS TABLE FROM THE INDUSTRY WILL PROBABLY AGREE WITH  
14    THAT POINT OF VIEW.

15                SO WE TRIED TO PUT SOME REAL TEETH IN HERE,  
16    BUT NOT THE SAME KIND OF REQUIREMENTS NECESSARILY  
17    WITHOUT THESE EMOLUMENTS WE HAVE HERE FOR A CURE  
18    PERIOD, ETC., IN THE MARCH-IN RIGHTS BECAUSE  
19    ESSENTIALLY PENALTY FOR FAILURE HERE IS SEEN AS MUCH  
20    GREATER.   THEREFORE, IN A SENSE, YOU NEED TO BE  
21    CAUTIOUS ABOUT HOW YOU WORD THIS.

22                MS. SAMUELSON:   IT SEEMS TO ME THAT THAT'S  
23    APPROPRIATE BECAUSE, AS I UNDERSTAND IT, WE'RE DOING  
24    SOMETHING QUITE NOVEL, WHICH IS THE INITIATIVE AND  
25    CERTAINLY THE VOTERS' EXPECTATION IS THAT WE'RE TYING

1 FUNDING TO AN EXPECTATION THAT WE NOT ONLY CONDUCT A  
2 BUNCH OF RESEARCH, BUT THAT WE DEVELOP EFFECTIVE  
3 THERAPIES OUT OF IT. THAT'S THE NET RESULT. IT SEEMS  
4 TO ME YOU'VE GOT TO HAVE SOME MECHANISMS TO KEEP --

5 DR. PENHOET: WE DO. AND THIS WAS A  
6 COMPROMISE WE CAME UP WITH TO ADDRESS THE FACT THAT WE  
7 DO HAVE SOME TEETH, WE CAN MARCH IN, BUT THAT WE CAN'T  
8 DO SO WITHOUT A HIGH BURDEN OF PROOF AND A CURE PERIOD.

9 DO ANY OTHER MEMBERS OF THE TASK FORCE WISH  
10 TO SPEAK TO THIS ISSUE? I SHOULDN'T BE ALWAYS  
11 ANSWERING THIS.

12 MR. GOLDBERG: I THINK YOU'VE ARTICULATED IT  
13 WELL.

14 MS. SAMUELSON: I LIKE THAT LANGUAGE. I'M  
15 JUST WONDERING IF THIS EARLIER LANGUAGE ACCOMPLISHES --  
16 IF I WERE A LAWYER REPRESENTING A COMPANY THAT DOESN'T  
17 WANT TO GIVE IT UP, EVEN THOUGH IT'S NOT MOVING A  
18 THERAPY AHEAD, I WOULD SAY, WELL, THEY HAVEN'T YET  
19 FULLY DEVELOPED THE RIGHTS GRANTED BECAUSE THEY MIGHT  
20 NEXT YEAR OR TEN YEARS FROM NOW.

21 DR. PENHOET: OKAY. YOUR COMMENTS ARE NOTED.  
22 ANY OTHER COMMENTS? DO I HAVE A MOTION FOR APPROVAL OF  
23 THE MARCH-IN RIGHTS?

24 MR. GOLDBERG: SO MOVED.

25 DR. LOVE: SECOND.

1 DR. PENHOET: SO MOVED GOLDBERG, SECONDED  
2 LOVE. ANY OTHER COMMENT?

3 MR. SIMPSON: JOHN SIMPSON FROM THE  
4 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I  
5 APPRECIATED THE QUESTION ABOUT THE ATTORNEY GENERAL. I  
6 SENSE THAT WAS DIRECTED MY WAY. IT DOES SEEM TO ME  
7 STILL YOU MENTION THE ATTORNEY GENERAL IN THE PREFACE,  
8 WHICH DOES NOT, AS I UNDERSTAND IT, END UP IN THE  
9 REGULATIONS. I WOULD THINK THAT YOU WOULD WANT TO  
10 REFLECT THE ATTORNEY GENERAL IN REGULATIONS SOMEWHERE,  
11 AND I DON'T SEE THAT HERE. THE LANGUAGE YOU USE IS MAY  
12 REFER. I WOULD STRONGLY URGE IT TO BE WILL REFER.

13 AND FINALLY, I THINK YOU NEED A FIFTH REASON  
14 TO MARCH IN, WHICH WOULD BE IN THE EVENT OF  
15 UNREASONABLE PRICING.

16 MR. REYNOLDS: JESSE REYNOLDS FROM THE CENTER  
17 FOR GENETICS AND SOCIETY. I'D LIKE TO ADD JUST A QUICK  
18 POINT ABOUT THE ISSUE ABOUT THE ATTORNEY GENERAL. THIS  
19 SECTION IS KEY BECAUSE THIS IS IN MANY WAYS SOME OF THE  
20 REAL TEETH ON A NUMBER OF THESE PROVISIONS,  
21 PARTICULARLY THE PROVISION AROUND FOLLOWING THROUGH  
22 WITH A PLAN -- WITH THE PLAN THAT LICENSEES DEVISE TO  
23 PROVIDE THERAPIES TO THE STATE'S UNINSURED.

24 AND I'M CONCERNED ABOUT THE PROVISION THAT  
25 IT'S THE RESPONSIBILITY OF THE CIRM TO REFER THE MATTER

1 TO THE ATTORNEY GENERAL. I FEEL THAT A REPRESENTATIVE  
2 OR AN AGENCY IN THE STATE THAT'S MORE DIRECTLY  
3 ACCOUNTABLE TO THE VOTERS IS ABLE TO TAKE ACTION ON HIS  
4 OR HER OWN, ESPECIALLY CONSIDERING THE STAFF  
5 LIMITATIONS AND THE INFREQUENCY OF THE MEETINGS OF THE  
6 BOARDS. I WOULDN'T WANT THE CIRM TO BE IN A POSITION  
7 WHERE IT HAS TO DETERMINE WHAT UNREASONABLE PRICING IS  
8 OR WHETHER THERE'S A PUBLIC EMERGENCY AND SO FORTH.  
9 THANK YOU.

10 DR. PRIETO: I HAVE TO TAKE SOME EXCEPTION TO  
11 THE COMMENT ABOUT THE INFREQUENCY OF THE MEETINGS OF  
12 THIS BOARD. BUT I WOULD ASK JAMES WHETHER THIS ISN'T  
13 STANDARD OPERATING PROCEDURE FOR A CALIFORNIA AGENCY.

14 MR. HARRISON: YES. THE ATTORNEY GENERAL HAS  
15 INHERENT CONSTITUTIONAL AUTHORITY TO ENFORCE THE LAWS  
16 OF THE STATE OF CALIFORNIA, INCLUDING THE REGULATIONS  
17 THAT ARE ADOPTED BY THIS BOARD.

18 DR. PRIETO: SPECIFICALLY ISN'T THIS  
19 GENERALLY BY REFERRAL FROM THE AGENCY?

20 MR. HARRISON: THAT'S CORRECT.

21 DR. PRIETO: ALL OF THIS IS INHERENT IN  
22 CALIFORNIA LAW?

23 MR. HARRISON: CORRECT.

24 DR. PENHOET: I'M SORRY. I'M GETTING PUNCHY  
25 UP HERE. DID WE HAVE A MOTION TO APPROVE THIS? ANY



1     ADDITIONAL COMMENTS BY THE BOARD OR BY THE PUBLIC? IF  
2     SO, ASK FOR THE MOTION, AND WE GOT A MOTION AND A  
3     SECOND. ALL IN FAVOR. OPPOSED? FINE. THANK YOU.

4             TWO LAST ISSUES UNDER SECTION III IN THE  
5     PUBLICATION POLICY ITEMS. WE RECEIVED A SUGGESTION  
6     FROM -- PAGE 26 OF YOUR DOCUMENT. WE RECEIVED A  
7     SUGGESTION FROM THE UCLA LIBRARY THAT WE ADD THE WORDS  
8     IN RED HERE. WE SAID *PUBMED CENTRAL*. THEY ASKED US TO  
9     CONSIDER ADDING OR ANY OTHER REPOSITORY THAT MEETS THE  
10    CRITERIA SET FORTH IN THE RESEARCH LIBRARY GROUP AND  
11    NATIONAL ARCHIVE AND RECORD ADMINISTRATION CRITERIA FOR  
12    A TRUSTED REPOSITORY.

13            WE'RE NOT HERE TO PUSH *PUBMED*. IT SEEMS LIKE  
14    A SENSIBLE ADDITION TO THIS. ANY DISCUSSION ABOUT THIS  
15    ADDITION?

16            DR. LOVE: I MOVE APPROVAL.

17            DR. WRIGHT: SECOND.

18            DR. PENHOET: SO MOVED. SECOND WRIGHT. ALL  
19    IN FAVOR. THANK YOU.

20            AND THE LAST ONE. WE ARE DONE. THAT IS THE  
21    LAST ONE. THANK YOU ALL FOR YOUR PATIENCE.

22            (APPLAUSE.)

23            CHAIRMAN KLEIN: DR. PENHOET, IF WE COULD  
24    PERHAPS HAVE THE IP TASK FORCE COMMITTEE MEMBERS JUST  
25    STAND. I THINK WE ALL OWE THEM A TREMENDOUS ROUND OF

1     APPLAUSE WITH DR. PENHOET'S LEADERSHIP AND MARY  
2     MAXON'S, AS I SAID, HEROIC ASSISTANCE. IT'S A  
3     TREMENDOUS EFFORT. COULD ALL THE IP TASK FORCE MEMBERS  
4     STAND.

5                     (APPLAUSE.)

6             CHAIRMAN KLEIN: THANK YOU VERY MUCH. THE  
7     INTENT RIGHT NOW IS TO HAVE A RELATIVELY SHORT BREAK;  
8     HOWEVER, THERE'S A REQUEST THAT IF THERE'S SOMEONE  
9     WHO'D LIKE A GENERAL PUBLIC COMMENT WHO HAS TO LEAVE  
10    BEFORE THE END OF THE SESSION, IF YOU COULD PLEASE MAKE  
11    THAT COMMENT VERY QUICKLY, REALIZING THE INTENSE  
12    LIMITATION ON TIME.

13            MR. ROMAN REED: LADIES AND GENTLEMEN, THANK  
14    YOU FOR YOUR TIME. LIKE THE VAST MAJORITY OF  
15    CALIFORNIANS WHO VOTED IN OVERWHELMING NUMBERS TO  
16    SUPPORT THE CALIFORNIA INSTITUTE FOR REGENERATIVE  
17    MEDICINE, I HAVE BEEN EXTREMELY FRUSTRATED BY THE  
18    ENDLESS OBJECTIONS AND ATTACKS ON THOSE WHO OPPOSE THE  
19    RESEARCH. THIS RESEARCH MUST COME THROUGH.

20            I KNOW EMPIRICALLY THAT STEM CELLS WORK.  
21    I'VE BEEN AFFORDED THE WONDERFUL OPPORTUNITY BY  
22    MR. OSWALD STEWARD AND HANS KIERSTED AT UC IRVINE TO  
23    HOLD IN MY HANDS A RAT THAT THE SPINAL CORD HAD BEEN  
24    COMPLETELY SEVERED. AND THIS RAT WAS GIVEN EMBRYONIC  
25    STEM CELL INJECTIONS, AND I FELT ITS LEGS MOVE AND I

1        SAW HIM WALK.

2                    WHAT YOU'RE FIGHTING FOR IS REAL. IT IS NOT  
3        A PIPE DREAM. IT IS WHAT'S GOING TO ONE DAY BE ABLE TO  
4        ALLOW ME FOR THE FIRST TIME IN MY LIFE TO BE ABLE TO  
5        PICK UP MY SON AND HOLD HIM HIGH. THIS IS SO  
6        IMPORTANT.

7                    MOST GOVERNMENT AGENCIES WITHOUT A BUDGET  
8        HAVE SIMPLY FOLDED THEIR TENTS AND GONE AWAY. BUT YOU,  
9        ESTEEMED LEADERSHIP OF THE CIRM, AND ESPECIALLY YOU,  
10       MR. BOB KLEIN, HAVE SOMEHOW FOUND A WAY TO KEEP MOVING  
11       AHEAD BY GOING OUT AND FINDING THE FUNDING AND THE  
12       BRIDGE GAP FUNDING THAT WE NEEDED. YOU HAVE KEPT  
13       CALIFORNIA'S HOPES AND DREAMS ALIVE. YOU HAVE KEPT THE  
14       PEOPLE WHO ARE SUFFERING, GAVE THEM REASON TO BELIEVE.

15                    LIKE THE SPIRIT OF CALIFORNIA ITSELF, THE  
16        CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE HAS BEEN  
17        FORWARD LOOKING, COMPASSIONATE, AND CREATIVE, AND  
18        UNSTOPPABLE. AND BECAUSE OF THIS, I HAVE EVERY  
19        CONFIDENCE THAT THESE MISGUIDED AND ERRONEOUS LAWSUITS  
20        WILL BE EXPOSED AS THE EMPTY DELAYING TACTICS THEY ARE.  
21        BECAUSE TO TRY AND THWART THE WILL OF THE MAJORITY OF  
22        THE PEOPLE IS WRONG. TO PURPOSELY UPHOLD THE CURES  
23        THAT WILL COME FROM STEM CELLS FOR THE PEOPLE WHO ARE  
24        SUFFERING IS IMMORAL. PEOPLE ARE GETTING WORSE AND  
25        WORSE AND DYING EVERY DAY THAT THESE STEM CELL CURES

1 ARE BEING WITHHELD BECAUSE OF SEMANTICS OR BECAUSE OF  
2 LAWSUITS. THAT IS NOT RIGHT.

3 SO I URGE YOU, EVERY MEMBER, TO PLEASE  
4 CONTINUE TO TAKE A STAND. TAKE A STAND FOR THE  
5 SUFFERING; AND BY DOING SO, ONE DAY EVERYBODY WILL BE  
6 ABLE TO STAND TOGETHER. THANK YOU VERY MUCH.

7 (APPLAUSE.)

8 CHAIRMAN KLEIN: THANK YOU VERY MUCH, ROMAN,  
9 FOR YOUR INSPIRATIONAL STATEMENT. AND I WOULD,  
10 HOWEVER, REMIND ALL OF US THAT IN MANY CASES THE  
11 TRANSITION FROM ANIMALS TO HUMANS MAY NOT WORK AT ALL.  
12 AND IN EVERY CASE IT IS HIGHLY LIKELY IT WILL TAKE  
13 MANY, MANY YEARS WITH MANY DISAPPOINTMENTS. SO LET'S  
14 KEEP OUR SPIRITS HIGH AND YOUR COMMITMENT HIGH BECAUSE  
15 IT WILL BE A LONG JOURNEY TO GET TO THESE GOALS WHERE  
16 WE MUST BE VERY PATIENT AND RESPECT AND ADMIRE THE  
17 INDIVIDUAL INCREMENTAL CHANGES IN KNOWLEDGE THAT WE GET  
18 FROM THE RESEARCH AS WE GO. ALL OF THOSE DESERVING  
19 VERY DISTINGUISHED RECOGNITION.

20 FOR THIS BREAK, THEY'VE ASKED -- THE PRESS  
21 HAS ASKED THE HONORABLE DR. ED PENHOET AND A COUPLE OF  
22 OTHERS TO STEP OUTSIDE FOR A QUICK INTERVIEW. WE ARE  
23 GOING TO GO INTO CLOSED SESSION. IF THE PUBLIC WOULD  
24 PLEASE LEAVE THE ROOM, WE'LL TRY AND KEEP THIS CLOSED  
25 SESSION TO 25 OR 30 MINUTES, SO BE PREPARED TO BE BACK

1 SOONER THAN YOU WOULD HAVE OTHERWISE.  
2 TWENTY-FIVE TO 30 MINUTES. WE'RE GOING TO BE  
3 IN CLOSED SESSION 25 TO 30 MINUTES.  
4 (A RECESS WAS TAKEN.)  
5 CHAIRMAN KLEIN: IF THE BOARD MEMBERS COULD  
6 BE SEATED FOR THE ROLL, THEN WE'LL KNOW THAT WE HAVE  
7 RECONFIRMED THE QUORUM TO COMMENCE THE SESSION. AND IF  
8 THE STAFF, DALE AND MARY, COULD YOU CHECK ON THE BOARD  
9 MEMBERS AND ASK THEM IF THEY COULD COME BACK IN TO  
10 RECONFIRM THE ROLL. THANK YOU.  
11 MS. KING: PAUL JENNINGS.  
12 DR. JENNINGS: HERE.  
13 MS. KING: ROBERT BIRGENEAU.  
14 DR. BIRGENEAU: HERE.  
15 MS. KING: DAVID MEYER.  
16 DR. MEYER: HERE.  
17 MS. KING: MARCY FEIT.  
18 MS. FEIT: HERE.  
19 MS. KING: MICHAEL FRIEDMAN.  
20 DR. FRIEDMAN: HERE.  
21 MS. KING: MICHAEL GOLDBERG. FRANCIS  
22 MARKLAND.  
23 DR. MARKLAND: HERE.  
24 MS. KING: ED HOLMES.  
25 DR. HOLMES: HERE.

1 MS. KING: DAVID KESSLER.  
2 DR. KESSLER: HERE.  
3 MS. KING: BOB KLEIN.  
4 CHAIRMAN KLEIN: HERE.  
5 MS. KING: SHERRY LANSING.  
6 MS. LANSING: HERE.  
7 MS. KING: TED LOVE. TINA NOVA.  
8 DR. NOVA: HERE.  
9 MS. KING: ED PENHOET.  
10 DR. PENHOET: HERE.  
11 MS. KING: PHIL PIZZO.  
12 DR. PIZZO: HERE.  
13 MS. KING: CLAIRE POMEROY. FRANCISCO PRIETO.  
14 DR. PRIETO: HERE.  
15 MS. KING: JOHN REED.  
16 DR. REED: HERE.  
17 MS. KING: JOAN SAMUELSON.  
18 MS. SAMUELSON: HERE.  
19 MS. KING: DAVID SERRANO-SEWELL.  
20 MR. SERRANO-SEWELL: HERE.  
21 MS. KING: JEFF SHEEHY.  
22 MR. SHEEHY: HERE.  
23 MS. KING: JONATHAN SHESTACK. OSWALD  
24 STEWARD.  
25 DR. STEWARD: HERE.

1 MS. KING: LEON THAL. JANET WRIGHT.

2 DR. WRIGHT: HERE.

3 MS. KING: AND I AM NOTING THAT MICHAEL  
4 GOLDBERG AND CLAIRE POMEROY ARE HERE, AND TED LOVE.

5 CHAIRMAN KLEIN: TED LOVE IS ALSO HERE.  
6 THANK YOU. OKAY.

7 IN ADDRESSING ITEM 9 ON THE AGENDA,  
8 CONSIDERATION OF THE PROPOSED DRAFT OF THE CIRM MEDICAL  
9 AND ETHICAL STANDARDS AND REGULATIONS FOR HUMAN STEM  
10 CELL RESEARCH, I'D LIKE TO CALL THE PUBLIC'S ATTENTION  
11 TO THE FACT THAT THERE WAS A GREAT OP ED PUBLISHED  
12 TODAY WRITTEN BY DR. BERNIE LO, SHERRY LANSING, AND  
13 ZACH HALL. I BELIEVE IT'S IN THE *CHRONICLE*; IS THAT  
14 CORRECT, DR. HALL, THAT REALLY ADDRESSES THIS SUBJECT  
15 AND THE OUTSTANDING WORK DONE CREATING A GOLD STANDARD  
16 ABOVE AND BEYOND THE REQUIREMENTS OF THE NATIONAL  
17 ACADEMY FOR CALIFORNIA TO LEAD THE WAY.

18 I WOULD LIKE TO TURN THIS OVER TO DR. HALL,  
19 WHO WILL LEAD THE INTRODUCTIONS OF THIS ITEM.

20 DR. HALL: GREAT. I WON'T TAKE LONG. I JUST  
21 WANTED TO SAY THAT THE WORKING GROUP HAS, AS YOU WILL  
22 HEAR, WORKED VERY LONG AND HARD OVER THE LAST SEVEN  
23 MONTHS OR SO TO WORK THROUGH THE VARIOUS ISSUES. THE  
24 WORKING GROUP IS CHAIRED BY SHERRY LANSING AND DR.  
25 BERNIE LO. AND SINCE MANY OF YOU HAVE NOT MET BERNIE

1       BEFORE, I WANT TO JUST BRIEFLY INTRODUCE HIM.

2               HE IS A MEMBER OF THE DEPARTMENT OF MEDICINE  
3       AT THE UNIVERSITY OF CALIFORNIA SAN FRANCISCO. HE'S  
4       THE DIRECTOR OF THE PROGRAM IN BIOETHICS THERE. HE'S A  
5       NATIONALLY DISTINGUISHED BIOETHICIST, HAVING BEEN ON  
6       THE NATIONAL BIOETHICS ADVISORY COMMISSION AND OTHER  
7       NATIONAL BODIES CONCERNED WITH ETHICS. WE'VE BEEN VERY  
8       PRIVILEGED ACTUALLY TO HAVE HIM SERVE AS VICE CHAIR OF  
9       THIS COMMITTEE, SO I NOW TURN THE MEETING OVER TO HIM.

10              DR. LO: THANK YOU VERY MUCH, ZACH. IT'S A  
11       REAL PLEASURE AND AN HONOR TO BE HERE TO PRESENT TO THE  
12       ICOC THE DRAFT GUIDELINES THAT THE STANDARDS WORKING  
13       GROUP HAS WORKED VERY HARD ON.

14              ON THE FIRST SLIDE I JUST WANT TO SORT OF  
15       ORIENT YOU TO WHAT I'M GOING TO TRY AND DO TODAY. I'M  
16       GOING TO GIVE YOU A BRIEF OVERVIEW TO REMIND YOU OF THE  
17       SWG AND THE PROCESS WE WENT THROUGH IN DRAFTING THESE  
18       REGULATIONS. AND THEN I'M GOING TO TRY AND JUST  
19       HIGHLIGHT FOR YOU THE DIFFERENCES BETWEEN THIS FINAL  
20       DRAFT VERSION AND THE INTERIM REGULATIONS WHICH YOU  
21       DELIBERATED ON AND APPROVED IN NOVEMBER OF LAST YEAR.

22              LET ME JUST START BY SAYING I'M VERY PROUD OF  
23       THE WORK THE SWG HAS DONE. I REALLY THINK THAT WE HAVE  
24       GONE SUBSTANTIALLY BEYOND THE CURRENT STANDARDS SET BY  
25       THE NATIONAL ACADEMY OF SCIENCES. AND I THINK I'M VERY



1     HAPPY TO BE ABLE TO PRESENT THESE TO YOU.

2             THE STANDARDS WORKING GROUP HAD 19 MEMBERS  
3     AND, AS YOU KNOW, WE COME FROM A VARIETY OF  
4     BACKGROUNDS.  THERE ARE SCIENTISTS AND CLINICIANS,  
5     THERE ARE PEOPLE WITH BACKGROUND IN LAW OR RESEARCH  
6     ETHICS, AND THAT WAS SPECIFICALLY IN THE LANGUAGE OF  
7     PROP 71 TO MAKE SURE THAT OUR SWG HAD EXPERTISE IN  
8     THOSE AREAS.  WE HAD A NUMBER OF PATIENT ADVOCATES, AND  
9     THERE WAS, I THINK, VERY GOOD DIVERSITY IN TERMS OF  
10    GEOGRAPHY, PEOPLE FROM OUT OF STATE, GENDER, AND ETHNIC  
11    BACKGROUND.

12            AND THE NEXT TWO SLIDES, I'M NOT GOING TO  
13    READ THEM THROUGH, BUT THE MEMBERS OF THE COMMITTEE  
14    HAVE HAD REALLY EXTENSIVE EXPERIENCE GOING BACK QUITE A  
15    LONG TIME SERVING ON NATIONAL AND STATE PANELS DEALING  
16    WITH HUMAN RESEARCH AND WITH STEM CELL RESEARCH IN  
17    PARTICULAR.  I WAS VERY FORTUNATE TO BE ABLE TO HAVE  
18    SUCH EXPERTISE ON OUR PANEL.

19            WE ALSO SENT OUT THE PENULTIMATE VERSION OF  
20    THE DRAFT GUIDELINES TO EXTERNAL REVIEWERS, AND WE WERE  
21    VERY FORTUNATE THAT THE CO-CHAIRS OF THE NATIONAL  
22    ACADEMY OF SCIENCES COMMITTEE, WHICH MADE GUIDELINES  
23    FOR HUMAN EMBRYONIC STEM CELL RESEARCH THAT WERE  
24    PROMULGATED IN MAY OF 2005, RICHARD HYNES FROM MIT AND  
25    JONATHAN MORENO FROM THE UNIVERSITY OF VIRGINIA, BOTH

1     REVIEWED THE MANUSCRIPT.  IT WAS REVIEWED BY THE  
2     INDIVIDUALS FROM THE HARVARD DEPARTMENT OF MOLECULAR  
3     AND CELLULAR BIOLOGY, AND HARRIET RABB, WHO'S VICE  
4     PRESIDENT AND GENERAL COUNSEL OF ROCKEFELLER AND  
5     PREVIOUSLY SERVED AS GENERAL COUNSEL FOR HHS, ALSO WAS  
6     GRACIOUS ENOUGH TO REVIEW THESE AND OFFER THEIR WISDOM.

7             NOW, THIS SLIDE SUMMARIZES THE PROCESS BY  
8     WHICH WE DEVELOPED THESE REGULATIONS.  AND WE HAD A  
9     SERIES OF MEETINGS, FIVE MEETINGS ALTOGETHER, ALL OF  
10    WHICH WERE OPEN TO THE PUBLIC.  AND I JUST WOULD LIKE  
11    TO PERSONALLY SAY THAT I THINK THE PUBLIC WAS  
12    WONDERFUL.  THEY PARTICIPATED ACTIVELY.  I THINK WE HAD  
13    A GOOD BACK-AND-FORTH DIALOGUE WHERE WE LEARNED A LOT  
14    FROM MEMBERS OF THE PUBLIC.  THEY REALLY BROUGHT UP  
15    ISSUES THAT REALLY DESERVED OUR ATTENTION, FRESH IDEAS,  
16    AND I THINK IN LARGE MEASURE THE STRENGTH OF THESE  
17    GUIDELINES IS A RESULT OF THIS VERY OPEN PUBLIC  
18    PROCESS.

19            WE ALSO HAD THREE PUBLIC SESSIONS FOR THE  
20    INTERIM GUIDELINES WHERE WE SPECIFICALLY SCHEDULED THEM  
21    AT SEVERAL LOCATIONS TO GET ADDITIONAL INPUT FROM  
22    PEOPLE WHO MIGHT NOT BE ABLE TO ATTEND OUR REGULAR  
23    MEETINGS.  WE ALSO HELD A ONE-DAY WORKSHOP CO-SPONSORED  
24    BY THE UNIVERSITY OF CALIFORNIA, OFFICE OF THE  
25    PRESIDENT, AND GLADSTONE INSTITUTE WAS GRACIOUS ENOUGH

1 TO HOST US WHERE WE INVITED RESEARCH INSTITUTIONS IN  
2 CALIFORNIA WHO ARE INTERESTED IN STEM CELL RESEARCH,  
3 BASICALLY ALL THE INSTITUTIONS THAT APPLIED FOR  
4 TRAINING GRANTS, TO COME AND GIVE US THEIR PERSPECTIVE.  
5 SO WE THINK WE HEARD FROM A LOT OF DIFFERENT  
6 STAKEHOLDERS IN THE STATE AND REALLY TRIED OUR BEST TO  
7 CONSIDER, THINK DEEPLY ABOUT THE ISSUES THEY RAISED.

8 SO TODAY WE'RE HERE TO PRESENT THESE TO YOU  
9 FOR YOUR CONSIDERATION. AND I'M GOING TO ASK, IF I  
10 MAY, JAMES HARRISON TO JUST QUICKLY REMIND US OF SORT  
11 OF WHERE WE GO FROM HERE BECAUSE THERE ARE A NUMBER OF  
12 ADDITIONAL STEPS IN TERMS OF THE ADMINISTRATIVE LAW  
13 PROCESS AND OPPORTUNITIES FOR MORE PUBLIC COMMENT AND  
14 FURTHER ICOC CONSIDERATION.

15 MR. HARRISON: AS ZACH POINTED OUT EARLIER  
16 THIS MORNING, WE ARE AT A DIFFERENT STAGE IN THE  
17 DEVELOPMENT OF THESE REGULATIONS THAN WE ARE WITH  
18 RESPECT TO THE IP POLICY. YOU AS A BOARD IN NOVEMBER  
19 ADOPTED INTERIM REGULATIONS TO GOVERN THE RESEARCH.  
20 WHAT YOU WERE DOING -- WHAT YOU ARE BEING ASKED TO DO  
21 TODAY IS TO ADOPT THESE AS PROPOSED REGULATIONS, WHICH  
22 WILL THEN GO THROUGH THE PROCESSES SET FORTH IN THE  
23 ADMINISTRATIVE PROCEDURE ACT, WHICH MEANS THAT THE  
24 OFFICE OF ADMINISTRATIVE LAW WILL PUBLISH THE PROPOSED  
25 REGULATIONS, THERE WILL BE A PUBLIC COMMENT PERIOD, AND

1 WE ANTICIPATE A PUBLIC HEARING AT WHICH THE PUBLIC WILL  
2 HAVE A FURTHER OPPORTUNITY TO COMMENT FOLLOWED BY AN  
3 OPPORTUNITY, AGAIN, FOR YOU TO REVIEW THE FINAL  
4 REGULATIONS AND ANY PROPOSED CHANGES THAT COME OUT OF  
5 THE PUBLIC COMMENTS. AND THEN THE OFFICE OF  
6 ADMINISTRATIVE LAW WILL HAVE 30 WORKING DAYS TO REVIEW  
7 THOSE REGULATIONS. AND AT THAT POINT IN TIME, THEY  
8 WILL BECOME FINAL AND REPLACE THE INTERIM REGULATIONS  
9 THAT ARE NOW IN PLACE.

10 CHAIRMAN KLEIN: JAMES, TO MAKE IT CLEAR FOR  
11 THE PUBLIC AND THE MEMBERS OF THIS BOARD, YOU SAY AN  
12 OPPORTUNITY FOR YOU TO REVIEW. THE ICOC WOULD REVIEW  
13 THOSE COMMENTS IN A PUBLIC MEETING AND TAKE ACTION IN A  
14 PUBLIC MEETING?

15 MR. HARRISON: THAT'S CORRECT.

16 MS. LANSING: EVEN AT THAT POINT, AND I THINK  
17 OUR WHOLE COMMITTEE IS REEMPHASIZING IT, EVEN AT THAT  
18 POINT AFTER ALL OF THAT, WE VIEW THIS AS A LIVING  
19 DOCUMENT, A DOCUMENT THAT AS THE SCIENCE CHANGES IS AN  
20 ONGOING PROCESS THAT WE'RE ALWAYS GOING TO READDRESS  
21 AND READDRESS AND READDRESS. AND WE SORT OF MADE A  
22 COMMITMENT TO THIS, LIFE COMMITMENT TO THIS.

23 DR. LO: THANKS, JAMES. I WANT JUST TO TAKE  
24 A MINUTE TO THANK A NUMBER OF PEOPLE WITHOUT WHOSE HARD  
25 WORK AND THOUGHT THIS DOCUMENT WOULDN'T HAVE BEEN

1     PRODUCED.  I WANT TO PARTICULARLY THANK GEOFF LOMAX AND  
2     KATE SHREVE AND SCOTT TOCHER OF THE CIRM FOR THEIR  
3     INVALUABLE ASSISTANCE.  IT COULDN'T HAVE BEEN DONE,  
4     GEOFF, AND WE REALLY THANK YOU.  I ALSO WANT TO AT THE  
5     RISK OF --

6                                 (APPLAUSE.)

7                 DR. LO:  I ALSO WOULD LIKE PUBLICLY TO REALLY  
8     STATE MY THANKS TO A NUMBER OF MEMBERS OF THE PUBLIC  
9     WHO HAVE VERY CAREFULLY FOLLOWED OUR WORK, COMMENTED  
10    EXTENSIVELY, REPEATEDLY, READ OUR WORK LINE BY LINE,  
11    AND I THINK REALLY HAVE GIVEN US SOME EXCELLENT IDEAS  
12    AND THINGS TO THINK ABOUT.  AT THE RISK OF SINGLING OUT  
13    SOME, I PARTICULARLY WANT TO THANK JESSE REYNOLDS, WHO  
14    I THINK WAS HERE.  I DON'T KNOW IF SUSAN FOGEL IS HERE.  
15    I DIDN'T SEE HER EARLIER.  ELLEN AURITI AND CHARIS  
16    THOMPSON, WHICH HAVE GIVEN US REALLY THOUGHTFUL  
17    COMMENTS.  I JUST WANT TO THANK THEM FOR THEIR HARD  
18    WORK AND THOUGHTFULNESS.

19                NOW, THE GUIDING PRINCIPLES OUR WORKING GROUP  
20    USED WERE, FIRST, TO USE THE NAS GUIDELINES, WHICH YOU  
21    APPROVED AS INTERIM GUIDELINES, BUT TO RECOGNIZE THAT  
22    WE REALLY NEEDED TO GO BEYOND THOSE.  FIRST, THE NAS  
23    ONLY ADDRESSED EMBRYONIC STEM CELLS.  THAT WAS THEIR  
24    CHARGE, AND OBVIOUSLY CIRM MAY BE FUNDING OTHER TYPES  
25    OF STEM CELL RESEARCH.  AND NAS REALLY MEANT TO GIVE

1 GUIDELINES THAT ARE APPLICABLE THROUGHOUT THE COUNTRY  
2 REGARDLESS OF SOURCE OF FUNDING. AND WE INTERPRETED  
3 OUR CHARGE REALLY STRICTLY AND NARROWLY, WHICH WAS TO  
4 WRITE REGULATIONS, NOT JUST GUIDELINES, BUT REGULATIONS  
5 FOR CIRM-FUNDED RESEARCH. AND WE HAD TO MAKE SURE THAT  
6 WE WEREN'T PUTTING THINGS IN THAT WERE REALLY GOING TO  
7 EXTEND BEYOND OUR APPROPRIATE REACH.

8 WE DECIDED TO INCORPORATE ALL PERTINENT  
9 EXISTING STATE AND FEDERAL LAWS AND REGULATIONS. THERE  
10 ARE FEDERAL REGULATIONS GOVERNING ALL RESEARCH WITH  
11 HUMAN BEINGS. CALIFORNIA HAS ADDITIONAL LAWS AND  
12 REGULATIONS APPLYING WITHIN THE STATE AND ADDITIONAL  
13 LAWS FOR STEM CELL RESEARCH. AND WE WANTED TO  
14 INCORPORATE ALL OF THOSE PROTECTIONS IN THESE  
15 GUIDELINES, BUT WE ALSO WANTED TO GO BEYOND THE  
16 EXISTING STANDARDS BECAUSE WE THOUGHT THAT THERE WERE A  
17 FEW PLACES WHERE WE COULD MAKE AN IMPROVEMENT.

18 NOW, THIS IS TO SUMMARIZE THE DOCUMENT THAT  
19 WAS IN YOUR BRIEFING BOOK, AND THE DARK BLUE BOXES,  
20 THESE FOUR BOXES ARE WHERE I'M GOING TO REALLY COMMENT  
21 ON. THE VERY PALE BOXES ARE NOT SIGNIFICANTLY CHANGED  
22 FROM WHAT YOU'VE SEEN, AND THE OTHER TWO MEDIUM BLUE  
23 I'LL COME BACK TO BRIEFLY AT THE END.

24 SO SCRO MEMBERSHIP, THE STEM CELL REVIEW  
25 ORGANIZATION MEMBERSHIP, AS YOU RECALL FROM YOUR

1 NOVEMBER DELIBERATIONS, EACH INSTITUTION RECEIVING CIRM  
2 FUNDING HAS TO SET UP THIS BODY, WHICH WAS ALSO  
3 RECOMMENDED BY THE NAS REPORT, TO PROVIDE OVERSIGHT AND  
4 REVIEW OF STEM CELL RESEARCH. I'M NOT GOING TO REPEAT  
5 THAT, BUT THE CURRENT INTERIM REGULATIONS REQUIRE  
6 EXPERTISE IN ALL SORT OF PERTINENT AND MULTIPLE  
7 DISCIPLINES.

8 THE PROPOSED DRAFT REGULATIONS MAKE TWO WHAT  
9 WE THINK ARE IMPORTANT ADDITIONS. ONE, THAT EVERY SCRO  
10 NEEDS TO HAVE AT LEAST ONE REPRESENTATIVE OF THE  
11 PUBLIC, AND WE DEFINE THAT CAREFULLY IN THE  
12 REGULATIONS, AND IN ADDITION AT LEAST ONE PATIENT  
13 ADVOCATE. AND WE THINK THESE TWO ADDITIONAL  
14 REQUIREMENTS FOR MEMBERSHIP WILL INCREASE TRANSPARENCY  
15 AND, WE THINK, BUILD PUBLIC TRUST IN THIS VERY, VERY  
16 IMPORTANT RESEARCH ENTERPRISE.

17 NOW, WE ALSO WANTED TO MAKE SURE THAT WE  
18 BUILD IN FLEXIBILITY, THAT STEM CELL RESEARCH IS NEW,  
19 THE SCRO'S ARE NEW, AND WE DIDN'T WANT TO BE OVERLY  
20 PRESCRIPTIVE IN TELLING INSTITUTIONS HOW TO WORK THINGS  
21 OUT WITHIN THEIR OWN INSTITUTIONAL ARRANGEMENT. SO IN  
22 RESPONSE TO SEVERAL QUERIES, WE STATE EXPLICITLY THAT  
23 IF SEVERAL INSTITUTIONS WANT TO JOIN TOGETHER TO CREATE  
24 ONE ESCRO, THAT'S PERMITTED. WE LEAVE OPEN THE  
25 POSSIBILITY OF A POSSIBLE CIRM-FUNDED SCRO FOR PART OF

1 THE STATE, AND WE DO NOT -- WE HAD A LOT OF QUESTIONS  
2 ABOUT THE TIMING OF REVIEW BY THE SCRO VERSUS OTHER  
3 BODIES SUCH AS THE EXISTING IRB'S, AND WE WANT TO LEAVE  
4 THAT UP TO THE INSTITUTION AS TO HOW TO WORK OUT THE  
5 TIMING. WE THINK THAT WILL DEPEND TREMENDOUSLY ON  
6 LOCAL FACTORS AND ALSO, FRANKLY, THAT PEOPLE AS THEY  
7 GET MORE EXPERIENCE WITH THIS RESEARCH AND MULTIPLE  
8 REVIEWS WILL FIGURE OUT WAYS TO DO IT BETTER. WE  
9 DIDN'T WANT TO PRESCRIBE TOO MUCH AT THE BEGINNING.

10 NOW, THE NEXT BIG TOPIC IS ACCEPTABLE STEM  
11 CELL LINES. SO WE WANTED TO SET STANDARDS FOR STEM  
12 CELL LINES THAT CIRM-FUNDED RESEARCHERS COULD WORK  
13 WITH. AND WE HAD TWO DIFFERENT WAYS THAT A STEM CELL  
14 LINE COULD QUALIFY FOR RESEARCH UNDER CIRM. ONE IS  
15 THAT IF IT HAD BEEN APPROVED OR DEPOSITED BY A NUMBER  
16 OF NATIONAL BODIES THAT HAVE ALREADY QUITE A BIT OF  
17 EXPERIENCE REVIEWING STEM CELL RESEARCH. SO IF IT'S  
18 ONE OF THOSE NIH-APPROVED STEM CELL LINES, IF THE STEM  
19 CELL LINE EITHER APPROVED BY THE UK HUMAN FERTILIZATION  
20 AND EMBRYOLOGY AUTHORITY OR DEPOSITED IN THEIR STEM  
21 CELL BANK OR APPROVED BY THE CANADIAN NATIONAL STEM  
22 CELL OVERSIGHT COMMITTEE, THOSE TWO OTHER COUNTRIES  
23 HAVE QUITE EXTENSIVE GUIDELINES AND REGULATIONS, AND  
24 ACTUALLY QUITE A BIT OF EXPERIENCE IN THE CASE OF THE  
25 UK DOING THIS, AND WE WANTED NOT TO HAVE THAT WORK OF



1 REVIEW BE DUPLICATED WHEN IT WAS ALREADY APPROVED BY  
2 ONE OF THOSE BODIES.

3 NOW, A SECOND WAY A STEM CELL LINE COULD BE  
4 ACCEPTABLE FOR CIRM-FUNDED RESEARCH WOULD BE IF THE  
5 STEM CELL LINE MET THESE FOUR CRITERIA. AND WE THINK  
6 IN A SENSE THESE ARE CORE ETHICAL STANDARDS THAT ANY  
7 STEM CELL LINE THAT CIRM RESEARCHERS WORK WITH, WHETHER  
8 IT'S DERIVED OUTSIDE OF THE STATE OR WITHOUT CIRM  
9 FUNDING, SHOULD MEET THESE CRITERIA.

10 FIRST, THAT THE DONORS GAVE FREE AND INFORMED  
11 CONSENT; THAT THE DONORS RECEIVED NO VALUABLE  
12 CONSIDERATION EXCEPT REIMBURSEMENT FOR EXPENSES. THIS  
13 TRACKS THE PROP 71 LANGUAGE, AND WE FELT THAT THIS IS  
14 SUCH A SENSITIVE ISSUE, THAT WE THOUGHT AT LEAST AT  
15 THIS TIME THAT WE SHOULD NOT ALLOW DONORS WHO WERE PAID  
16 BEYOND THEIR EXPENSES. WE ALSO REQUIRE STEM CELL  
17 LINES, THAT THERE BE NO PAYMENT FOR STORAGE OF  
18 MATERIALS BEFORE THE DECISION TO DONATE. SO THAT'S  
19 ANOTHER WAY THAT PEOPLE MIGHT GET CONSIDERATION FOR  
20 PAYMENT OF STORAGE FEES, FOR EXAMPLE, FOR FROZEN  
21 EMBRYOS. AND THAT STEM CELL LINE DERIVATION PROCESS BE  
22 OVERSEEN BY AN IRB.

23 SO THE CORE PROTECTIONS WE GIVE IN ALL HUMAN  
24 SUBJECTS RESEARCH, REQUIREMENT OF CONSENT AND IRB  
25 OVERSIGHT, WE WANT ANY STEM CELL LINE THAT CIRM

1 RESEARCHERS ARE FUNDED TO USE TO HAVE GONE THROUGH  
2 THOSE OVERSIGHT PROCESSES. AND WE DON'T ALSO WANT  
3 NECESSARILY -- WE DON'T NEED THAT TO BE REDONE A SECOND  
4 TIME BY THE CIRM INVESTIGATOR IF THIS HAS ALREADY BEEN  
5 DONE.

6 NOW, THERE WILL BE ALSO, WE THINK -- IT MAY  
7 ALSO BE LIKELY THAT CIRM WILL FUND RESEARCHERS TO  
8 DERIVE NEW STEM CELL LINES WITH CIRM FUNDING. AND FOR  
9 THAT RESEARCH DONE WITHIN CALIFORNIA WITH CIRM FUNDS,  
10 WE THOUGHT THERE SHOULD BE EVEN HIGHER STANDARDS. WE  
11 WERE RELUCTANT TO IMPOSE STANDARDS OUTSIDE OF  
12 CALIFORNIA, PARTICULARLY IN COUNTRIES WHERE THEY MAY  
13 NOT BE NEEDED, BUT WE THOUGHT IN CALIFORNIA WE SHOULD  
14 GO BEYOND THIS. AND WE WANT TO HAVE HEIGHTENED  
15 INFORMED CONSENT REQUIREMENTS FOR CIRM-FUNDED  
16 DERIVATION OF NEW STEM CELL -- CIRM-FUNDED RESEARCH.  
17 AND ALSO, IF THERE'S DERIVATION OF NEW STEM CELL LINES,  
18 ADDITIONAL PROTECTION FOR OOCYTE DONORS AND VERY  
19 METICULOUS RECORDKEEPING SO THAT ALL GAMETES, EMBRYOS,  
20 OR PRODUCTS OF SCNT, THERE BE A TRACKING OF EACH CELL.

21 THE REASON WE WANTED TO INCLUDE BOTH MORE  
22 HEIGHTENED INFORMED CONSENT AND ADDITIONAL PROTECTIONS  
23 FOR OOCYTE DONORS IS THAT WITH THE RECENT NEWS, THERE'S  
24 BEEN A LOT OF CONCERN ABOUT COULD THERE BE MISCONDUCT  
25 IN THIS PUBLICLY FUNDED RESEARCH. AND WE WANTED TO

1 MAKE SURE THAT WE HAD REASONABLE, BUT NOT BURDENSOME  
2 PROTECTIONS TO REASSURE THE PUBLIC THAT ALL WORK BEING  
3 DONE WITH CIRM FUNDING WOULD, IN FACT, BE DONE TO VERY  
4 HIGH ETHICAL STANDARDS.

5 NOW, LET ME TRY AND WALK YOU THROUGH THE  
6 HEIGHTENED INFORMED CONSENT PROCESS FOR CIRM-FUNDED  
7 RESEARCH. FIRST, WE WANTED TO HAVE EXTENSIVE  
8 DISCLOSURE DURING THE INFORMED CONSENT PROCESS, AND WE  
9 ADOPTED CALIFORNIA LAWS AS WELL AS FEDERAL LAWS AND  
10 REGULATIONS THAT SPELL OUT IN REALLY SOME DETAIL WHAT  
11 CONSENT -- WHAT MUST BE DISCLOSED PARTICULARLY TO WOMEN  
12 DONATING OOCYTES. WE ALSO PUT IN A SET OF PROVISIONS  
13 REALLY HAVING TO DO WITH FUTURE USES OF STEM CELL  
14 LINES.

15 AND I WANTED TO SORT OF GIVE YOU SOME  
16 BACKGROUND HERE. ONE OF THE EXCITING THINGS,  
17 OBVIOUSLY, ABOUT STEM CELL RESEARCH IS THAT THESE LINES  
18 CAN BE PROPAGATED FOR QUITE A PERIOD OF TIME IN THE  
19 LABORATORY. IF THEY'RE SHARED WITH OTHER RESEARCHERS  
20 UNDER THESE PROVISIONS, THE IP PROVISIONS THAT YOU  
21 DISCUSSED THIS MORNING, OTHER SCIENTISTS WILL TAKE  
22 THEM, MANIPULATE THEM, WORK WITH THEM, DO NEW RESEARCH,  
23 AND IT'S QUITE POSSIBLE THAT IF YOU DONATE MATERIALS TO  
24 DERIVE NEW STEM CELL LINES, MONTHS OR YEARS DOWN THE  
25 ROAD, A RESEARCHER WILL WANT TO USE THOSE CELL LINES

1 FOR PROJECTS THAT WERE NOT CONCEIVED OF AT THE TIME OF  
2 THE ORIGINAL DONATION. AND THE REAL QUESTION IS HOW  
3 CAN PEOPLE GIVE CONSENT FOR RESEARCH THAT WILL TAKE  
4 PLACE YEARS IN THE FUTURE THAT NO ONE PERHAPS EVEN  
5 THOUGHT OF AT THE TIME.

6 AND WE TRIED TO APPROACH THAT IN THE  
7 FOLLOWING WAY. ONE, WE THINK THAT RESEARCHERS SHOULD  
8 NOT VIOLATE ANY DOCUMENTED PREFERENCES THAT DONORS  
9 HAVE. SO IF A DONOR SAYS I'M A SUPPORTER OF STEM CELL  
10 RESEARCH, BUT I DON'T WANT MY RESEARCH USED FOR THIS  
11 PARTICULAR TYPE OF RESEARCH DOWN THE ROAD, WE THINK  
12 THAT SHOULD BE HONORED AS A MATTER OF RESPECTING THE  
13 AUTONOMY -- THE INFORMED WISHES OF THE DONOR.

14 WE ALSO THINK IT'S IMPORTANT THAT THE DONORS  
15 BE GIVEN AN OPPORTUNITY TO DOCUMENT THEIR PREFERENCES.  
16 ALL THE TIME WHEN YOU GO INTO A HOSPITAL, YOU'RE ASKED  
17 TO SIGN A BLANKET CONSENT THAT ANY MATERIAL LEFT OVER  
18 FROM YOUR CLINICAL CARE, YOU GIVE DR. LO AND HIS  
19 ASSOCIATES PERMISSION TO USE IT FOR TEACHING AND  
20 RESEARCH. YOU DON'T REALLY KNOW WHAT THAT MEANS, AND  
21 WE FELT UNCOMFORTABLE HAVING THAT KIND OF BLANKET  
22 CONSENT. WE WANTED THE DONORS TO REALLY THINK ABOUT  
23 THIS.

24 AND THE OTHER HAND, WE ALSO WANTED TO  
25 EXPLICITLY ALLOW RESEARCHERS TO INCLUDE AS DONORS FOR

1 NEW STEM CELL LINES ONLY PEOPLE WHO WOULD AGREE TO ALL  
2 FUTURE USES OF THEIR STEM CELL LINES DERIVED FROM THEIR  
3 MATERIALS PROVIDED, OF COURSE, IT WAS REVIEWED,  
4 APPROVED BY AN IRB AND SCRO, AND ALSO THAT IT WAS  
5 APPROVED FOR SCIENTIFIC MERIT.

6 BASICALLY WHAT WE THINK NEEDS TO HAPPEN HERE  
7 IS SOMEONE DONATING MATERIALS FOR A NEW STEM CELL LINE  
8 UNDER CIRM FUNDING IN CALIFORNIA, MOST OF THE TIME  
9 THEY'RE GOING TO HAVE TO PUT THEIR TRUST IN THIS ENTIRE  
10 CIRM ENTERPRISE TO SAY I CAN'T PREDICT EXACTLY AND  
11 NEITHER CAN YOU SCIENTISTS TELL ME EXACTLY WHAT WILL BE  
12 DONE WITH MY CELLS BY OTHER SCIENTISTS; BUT AS LONG AS  
13 IT UNDERGOES SCIENTIFIC REVIEW AND ETHICAL REVIEW, I  
14 GIVE MY PERMISSION. WE THINK THAT'S KIND OF THE SPIRIT  
15 IN WHICH NEW STEM CELL LINES SHOULD BE DERIVED. THIS  
16 GOES QUITE A BIT BEYOND, WE THINK, WHAT IS REQUIRED IN  
17 REGULATIONS AND GUIDELINES ELSEWHERE IN THE COUNTRY.

18 NOW, WE ALSO ADDED SOME ADDITIONAL PROVISIONS  
19 FOR OOCYTE DONORS. AND, AGAIN, JUST TO SORT OF GIVE  
20 YOU A LITTLE BIT OF BACKGROUND, OOCYTE DONATION IS  
21 OBVIOUSLY VERY SENSITIVE GIVEN THE NATURE OF THESE  
22 REPRODUCTIVE CELLS. PEOPLE HAVE VERY STRONG FEELINGS  
23 ABOUT THEM, AND THERE HAVE BEEN CONCERNS RAISED IN THE  
24 PUBLIC AND BY SENATOR ORTIZ AND OTHERS IN THE  
25 LEGISLATURE ABOUT WHAT ARE THE RISKS OF OOCYTE

1       RETRIEVAL AS IT'S NOW CURRENTLY DONE?

2                   FOR CIRM-FUNDED RESEARCH USING OOCYTE DONORS,  
3       WE SPECIFY ADDITIONAL DISCLOSURE REGARDING RISKS,  
4       PARTICULARLY THE SHORT-TERM RISKS OF THE OOCYTE  
5       RETRIEVAL PROCESS. WE ALSO WENT BEYOND THAT TO ASK  
6       RESEARCHERS TO ASCERTAIN THAT THE DONOR UNDERSTANDS  
7       ESSENTIAL ASPECTS OF THE RESEARCH. LET ME, IF I MAY,  
8       TAKE A MINUTE TO GIVE YOU THE BACKGROUND OF THAT.

9                   THERE ARE A NUMBER OF EMPIRICAL STUDIES DONE  
10      OF RESEARCH IN OTHER CONTEXTS, NOT THE OOCYTE DONATION  
11      CONTEXT, BUT OTHER RESEARCH CONTEXT THAT SHOWS THAT  
12      EVEN AFTER YOU GO THROUGH AN IRB-APPROVED CONSENT  
13      PROCESS AND SIGN THE CONSENT FORM, MANY INDIVIDUALS IN  
14      THAT RESEARCH HAVE SERIOUS MISUNDERSTANDINGS ABOUT THE  
15      NATURE, THE PURPOSE OF THE RESEARCH, AND WHAT WILL BE  
16      DONE.

17                  WE THINK THAT IN THE CONTEXT OF OOCYTE  
18      DONATION WE NEED TO TRY AND CORRECT MISUNDERSTANDINGS  
19      TO THE EXTENT THAT'S POSSIBLE. SO WE THINK THERE'S A  
20      RATIONALE FOR TRYING TO ASSESS UNDERSTANDING, AND  
21      THERE'S ACTUALLY BEEN A MODERATE AMOUNT OF EXPERIENCE,  
22      AGAIN, NOT IN THE OOCYTE DONATION SETTING, BUT IN  
23      RESEARCH ABOUT INFORMED CONSENT AND IN CERTAIN TYPES OF  
24      RESEARCH THAT THESE KINDS OF -- I DON'T KNOW IF QUIZZES  
25      IS THE RIGHT WORD, BUT ASKING QUESTIONS OF THE RESEARCH

1 PARTICIPANT TO GET A SENSE OF WHAT THEY UNDERSTAND, AND  
2 THEN TRY AND EXPLAIN MORE. THAT'S DONE, FOR EXAMPLE,  
3 IN MANY HIV PREVENTION AND TREATMENT TRIALS IN  
4 DEVELOPING COUNTRIES WHERE, AGAIN, THERE'S BEEN THIS  
5 CONCERN THAT PEOPLE DON'T UNDERSTAND WHAT THEY AGREED  
6 TO. WELL, IF YOU ASK THEM WHAT THEY AGREED TO AND TALK  
7 TO THEM ABOUT IT, THEY'RE MORE LIKELY TO UNDERSTAND.

8 SO WE THINK -- I TAKE VERY MUCH TO HEART THE  
9 DISCUSSION YOU HAD BEFORE LUNCH ABOUT WRITING  
10 REGULATIONS THAT BREAK NEW GROUND, NOT WANTING TO  
11 OVERSTEP AND PUT THINGS IN THAT EITHER WON'T WORK OR  
12 ARE UNDULY BURDENSOME OR HAVE UNANTICIPATED ADVERSE  
13 EFFECTS. WE THINK THIS IS A SITUATION WHERE THERE'S  
14 SOME PRECEDENT FOR WHAT WE'RE DOING, BUT WE'RE  
15 REQUIRING IT, AND WE'RE ALSO EXTENDING IT TO A DISCRETE  
16 SEGMENT OF RESEARCH.

17 ANOTHER PROTECTION WE WANT TO PUT IN IS THAT  
18 THERE BE ADEQUATE TIME FOR THE OOCYTE DONOR TO  
19 DELIBERATE ABOUT WHAT'S A PRETTY INVOLVED PROCESS. AND  
20 WE DON'T WANT THESE DECISIONS TO BE MADE WITHOUT  
21 ADEQUATE DELIBERATION.

22 I'M GOING TO SKIP OVER THE NEXT SLIDES, WHICH  
23 ARE DETAILS ABOUT WHAT WE'RE ASKING TO BE DISCLOSED AND  
24 WHAT WE'RE ASKING PEOPLE TO SHOW UNDERSTANDING OF. LET  
25 ME JUST SAY THAT THE REGULATIONS SAY THAT THE

1 RESEARCHERS MUST HAVE A PROCESS IN PLACE TO ASSESS  
2 UNDERSTANDING. WE LEAVE IT UP TO THE INDIVIDUAL IRB  
3 AND THE SCRO, FOR THAT MATTER, TO DETERMINE WHETHER THE  
4 PROCESS THAT'S PROPOSED IS APPROPRIATE OR NOT. WE DO  
5 NOT WANT TO TRY AND MICROMANAGE EVERY RESEARCH PROJECT.  
6 WE WANT TO SET A GOAL, A STANDARD, AND LEAVE IT UP TO  
7 THE INSTITUTIONAL REVIEW PROCESS TO MAKE THE ASSESSMENT  
8 OF WHETHER THE PARTICULAR PROCEDURE AND PROTOCOL IS  
9 ADEQUATE OR NOT. AGAIN, THIS IS SOMETHING THAT THE  
10 SCRO'S ARE GOING TO LEARN TO DO AND IRB'S ALREADY HAVE  
11 A LOT OF EXPERIENCE WITH. SO WE WANT THAT FLEXIBILITY  
12 IN HOW THEY WILL ACHIEVE THE GOAL THAT WE'VE SET FORTH.

13 NOW, IN ADDITION, WE HAVE YET SEVERAL MORE  
14 ADDITIONAL PROTECTIONS FOR OOCYTE DONORS. AND, AGAIN,  
15 THIS BREAKS NEW GROUND, AND I'LL TRY AND EXPLAIN THE  
16 BACKGROUND FOR THIS. THERE'S NO QUESTION THAT THERE IS  
17 A RISK, ALBEIT A SMALL RISK, OF SHORT-TERM  
18 COMPLICATIONS OF THE OOCYTE RETRIEVAL PROCESS. THERE'S  
19 A HYPEROVULATION SYNDROME WHICH CAN CAUSE PAIN,  
20 PERITONEAL SIGNS, YOU CAN HAVE BLEEDING, YOU CAN HAVE  
21 INFECTION, YOU CAN HAVE COMPLICATIONS OF ANESTHESIA,  
22 YOU CAN BECOME PREGNANT BECAUSE NOT ALL THE MATURE  
23 OOCYTES MAY HAVE BEEN RETRIEVED. THERE MAY BE MEDICAL  
24 COSTS ASSOCIATED WITH TAKING CARE OF THOSE SHORT-TERM  
25 COMPLICATIONS. AND WE THOUGHT, AS A MATTER OF FAIRNESS



1 OR RECIPROCITY, THAT WOMEN WHO AREN'T BEING PAID, WHO  
2 ARE VOLUNTEERING, WHO ARE ONLY BEING REIMBURSED FOR  
3 EXPENSES SHOULD NOT HAVE TO SHOULDER THE COSTS OF  
4 MEDICAL CARE.

5           YOU SAY A LOT OF THESE PEOPLE WILL BE  
6 INSURED. WELL, THAT'S TRUE, BUT THERE MAY BE  
7 COPAYMENTS, THERE MAY BE DEDUCTIBLES. AND GIVEN OUR  
8 HEALTHCARE INSURANCE SYSTEM OR UNSYSTEM IN THIS STATE,  
9 A WOMAN MAY NEED TO APPLY AS AN INDIVIDUAL AND BE  
10 SUBJECT TO HAVING A RECORDS REVIEW. WE THOUGHT FOR  
11 MANY REASONS IT WOULD BE DESIRABLE NOT TO HAVE THE  
12 WOMAN HAVE TO PAY THE COST OF THOSE SHORT-TERM  
13 IMMEDIATE RISKS. WE PUT IT ON THE INSTITUTION TO  
14 ASSUME THAT COST OF CARE, LEAVE IT TO THE INSTITUTION  
15 TO FIGURE THAT OUT.

16           NOW, WE REALIZE THIS IS A COMPLICATED  
17 PROCESS. THERE ARE SOME INSTITUTIONS THAT ARE TRYING  
18 TO DO THAT. I KNOW THE UC SYSTEM IS TRYING TO THINK  
19 ABOUT HOW TO DO IT. IT'S VERY COMPLICATED. WE TRIED  
20 TO MAKE IT EASIER BY SAYING THERE'S NO LONG TAIL HERE.  
21 WE'RE REALLY TALKING ABOUT THE SHORT-TERM IMMEDIATE  
22 CONSEQUENCES WHICH SHOULD BE FAIRLY EASY TO CALCULATE  
23 ON AN ACTUARIAL BASIS. AT OUR LAST MEETING WE WERE  
24 TOLD THAT THERE ACTUALLY IS COMMERCIALY AVAILABLE  
25 INSURANCE FOR EXACTLY THESE KINDS OF COMPLICATIONS IN

1 THE OOCYTE DONATION CONTEXT OF AN INFERTILITY CLINIC.

2 SO WE THINK THIS IS AN IMPORTANT STEP. WE  
3 DON'T THINK IT'S UNREASONABLE. WE DON'T THINK IT'S  
4 GOING TO BE UNDULY BURDENSOME TO TRY AND IMPLEMENT, BUT  
5 WE THINK IT WILL GO A LONG WAY TOWARDS NOT ASKING TOO  
6 MUCH OF OOCYTE DONORS.

7 A SECOND PROTECTION WE WANTED TO PUT IN HAS  
8 TO DO WITH A VERY PARTICULAR SITUATION. AND THAT'S  
9 WHEN A WOMAN IS DONATING OOCYTES BOTH TO CIRM-FUNDED  
10 RESEARCHERS AND TO A WOMAN WHO'S UNDERGOING TREATMENT  
11 IN AN ASSISTED REPRODUCTION CLINIC. SHE MAY BE TRYING  
12 TO GET PREGNANT HERSELF, OR SHE MAY BE DONATING OOCYTES  
13 TO AN INFERTILE WOMAN. IT SEEMS TO ME WE WERE  
14 CONCERNED OF THE COMPLEXITY OF THAT ETHICAL SITUATION  
15 WHERE THE WOMAN WHO'S INFERTILE AND IS TRYING TO GET  
16 PREGNANT, SHE MAY NEED EVERY OOCYTE THAT CAN BE  
17 RETRIEVED. AND TO GIVE SOME TO RESEARCHERS MAY  
18 ACTUALLY HARM HER REPRODUCTIVE GOALS.

19 SO WE WANTED TO SAY IF THAT SITUATION OCCURS,  
20 THAT THE WAY THE DONOR IS HANDLED SHOULD NOT COMPROMISE  
21 THE OPTIMAL REPRODUCTIVE SUCCESS OF THE WOMAN IN  
22 INFERTILITY TREATMENT.

23 FINALLY, WE WANTED TO BE SENSITIVE TO  
24 POTENTIAL CONFLICTS OF INTEREST OR POTENTIAL CONFLICTS  
25 OF INTEREST ON THE PART OF THE PHYSICIAN WHO'S ACTUALLY

1     MANAGING THE OOCYTE RETRIEVAL PROCESS FOR THESE  
2     RESEARCH OOCYTES.  WE DIDN'T WANT THAT ATTENDING  
3     PHYSICIAN TO BE THE PRINCIPAL INVESTIGATOR ON THE CIRM  
4     GRANT BECAUSE HE/SHE MIGHT BE PULLED IN TWO DIFFERENT  
5     DIRECTIONS.

6             THERE'S AN AMENDMENT IN YOUR SHEETS TO ALSO  
7     SAY THAT THE ATTENDING PHYSICIAN NEEDS TO DISCLOSE HIS  
8     RELATIONSHIP TO THE RESEARCH TEAM AND FUNDING, AND THE  
9     ATTENDING PHYSICIAN IN THE OOCYTE DONATION MAY NOT HAVE  
10    A FINANCIAL STAKE IN THE OUTCOME OF THE RESEARCH.  WE  
11    THINK THESE WERE PROTECTIONS THAT NEEDED TO BE PUT IN  
12    PLACE, AGAIN, TO PROTECT AGAINST EVEN THE APPEARANCE OF  
13    A CONFLICT OF INTEREST.  AND, AGAIN, THIS IS NOT UNLIKE  
14    WHAT'S DONE, FOR EXAMPLE, IN THE TRANSPLANTATION  
15    CONTEXT WHERE THERE'S A SEPARATION OF ROLES.

16            SO LET ME JUST HIGHLIGHT FOR YOU THESE TWO  
17    LIGHT BLUE BOXES, COMPLIANCE, WHICH YOU'LL HEAR ABOUT  
18    LATER, AND REFER YOU BACK TO THE MATERIALS SHARING THAT  
19    YOU HEARD THIS MORNING.  WE VERY MUCH VIEW OUR  
20    RECOMMENDATIONS AS BEING PART OF A PACKAGE TOGETHER  
21    WITH THE IP RECOMMENDATIONS AND WITH THE GRANTS  
22    MANAGEMENT POLICY THAT YOU WILL HEAR ABOUT LATER, AND  
23    THAT THERE ARE A LOT OF ISSUES HAVING TO DO WITH  
24    COMPLIANCE, ENFORCEMENT WHICH WE PUT IN SOME TO OUR  
25    REGULATIONS, BUT WE REALLY ARE DEFERRING TO THE MUCH

1 MORE SORT OF DETAILED REGULATIONS THAT THE GRANTS  
2 WORKING GROUP WILL PRESENT YOU WITH.

3 AND ALSO IN TERMS OF THE MATERIALS SHARING,  
4 WE JUST WANT TO HIGHLIGHT FOR YOU THAT SHARING  
5 MATERIALS IS GOOD FOR MANY, MANY REASONS. AND AN  
6 ADDITIONAL REASON IS THAT WE THINK IT SERVES AS A  
7 SAFEGUARD AGAINST MISCONDUCT. TO THE EXTENT THAT YOU  
8 SHARE YOUR MATERIALS WITH OTHER SCIENTISTS TO TRY AND  
9 REPLICATE YOUR WORK, BUILD UPON IT, IT REALLY SERVES AS  
10 A BIG DISINCENTIVE TO TRY AND COMMIT THE KINDS OF  
11 SCIENCE MISCONDUCT THAT WE'VE SEEN IN SOUTH KOREA.

12 SO LET ME TRY TO CONCLUDE BY SAYING I'M  
13 PLEASED TO PRESENT TO YOU, THE ICOC, FOR YOUR  
14 CONSIDERATION THESE DRAFT REGULATIONS. WE ASK YOU TO  
15 TAKE THE NEXT STEP IN THIS REGULATORY PROCESS OF  
16 APPROVING THESE REGULATIONS SO THEY CAN BE SENT TO THE  
17 OFFICE OF ADMINISTRATIVE LAW AND BEGIN THIS FORMAL  
18 PUBLIC COMMENTARY PERIOD TO WHICH WE WILL THEN HAVE TO  
19 RESPOND TO THOSE PUBLIC COMMENTS, AND HAVE THE ICOC  
20 DEAL WITH THEM AS WELL.

21 I JUST WANT TO ADD ON A PERSONAL NOTE BY  
22 SAYING I'M TREMENDOUSLY PROUD OF THE WORK THIS PANEL  
23 HAS DONE. I'M VERY PROUD OF THOSE REGULATIONS. I  
24 THINK IT'S A REALLY BIG STEP FORWARD IN MAKING SURE  
25 THIS RESEARCH IS ON A VERY FIRM ETHICAL FOOTING. I

1 THINK IT'S SOMETHING THAT THE PEOPLE OF CALIFORNIA CAN  
2 BE VERY PROUD OF. THANK YOU.

3 (APPLAUSE.)

4 DR. LO: TECHNICALLY GEOFF REMINDS ME THAT  
5 TECHNICALLY WE'RE ASKING YOU TO APPROVE WITH THE  
6 ATTACHMENT THAT YOU GOT IN YOUR BRIEFING BOOK, THERE  
7 ARE FOUR OMISSIONS OR MISSTATEMENTS THAT ACTUALLY WERE  
8 CALLED TO OUR ATTENTION BY OUR VERY HELPFUL MEMBERS OF  
9 THE PUBLIC, AND WE WANT YOU TO APPROVE THOSE AS WELL AS  
10 THE THICK STAPLED DOCUMENT WITH THE PRETTY BOX THAT  
11 LOOKS LIKE THAT.

12 ICOC COMMENTS AND PUBLIC COMMENTS AS WELL.

13 DR. KESSLER: BERNIE, I THINK I CAN PROBABLY  
14 SPEAK FOR EVERYBODY. THAT WAS PROBABLY ONE OF THE MOST  
15 PHENOMENAL PRESENTATIONS THAT I HAVE HEARD.

16 (APPLAUSE.)

17 DR. KESSLER: MY ONLY COMMENT, A MOST  
18 THOUGHTFUL AND REASONED DOCUMENT. YOU REALLY HAVE  
19 SERVED THE PEOPLE OF CALIFORNIA VERY WELL.

20 DR. LO: THANK YOU. ARE THERE ICOC COMMENTS?

21 CHAIRMAN KLEIN: ALL RIGHT. DO WE HAVE ICOC  
22 COMMENTS HERE AT THIS POINT?

23 MS. SAMUELSON: COULD WE JUST HAVE THE  
24 SUBCOMMITTEE OR WHATEVER THEY ARE STAND SO WE CAN SEE  
25 WHO THEY ARE AND ALSO RECOGNIZE OUR APPRECIATION?

1 DR. LO: I'D LIKE TO PARTICULARLY SORT OF  
2 SINGLE OUT SHERRY LANSING, THE CO-CHAIR, WHO'S BEEN  
3 TERRIFIC. AND JEFF SHEEHY, JON SHESTACK, FRANCISCO  
4 PRIETO. THANK YOU ALL VERY MUCH.

5 I MUST SAY I'M IN TOTAL AWE OF THESE PATIENT  
6 ADVOCATES WHO SERVE NOT JUST ON OUR COMMITTEE, WHICH  
7 SEEMS LIKE A FULL-TIME JOB, BUT ON THE ICOC AND OTHER  
8 COMMITTEES AS WELL. I THINK THEY'VE REALLY DONE US ALL  
9 A WONDER SERVICE, AND WE THANK YOU.

10 MS. LANSING: I JUST WANT TO SAY PUBLICLY  
11 THAT WORKING WITH BERNIE WAS ONE OF THE GREAT HONORS OF  
12 MY LIFE. AND AS YOU CAN SEE BY HIS PRESENTATION, HE IS  
13 AN EXTRAORDINARY PERSON OF THE HIGHEST INTEGRITY AND OF  
14 AN INTELLECT THAT SURPASSES ANYTHING.

15 AND AS WERE ALL THE OTHER COMMITTEE MEMBERS  
16 THAT ARE NOT HERE, THE COUNTLESS HOURS THAT WENT INTO  
17 THIS BACK AND FORTH AND THE MEMBERS OF THE PUBLIC AND  
18 THE MEMBERS OF THE LEGISLATURE AND, AGAIN, I SAY THAT  
19 THIS IS THE BEGINNING. AND WE WILL KEEP WORKING ON  
20 THIS AS THE SCIENCE CHANGES, AND WE WILL KEEP BEING  
21 FLEXIBLE AND ADAPTING.

22 BERNIE, I CANNOT THANK YOU ENOUGH.

23 CHAIRMAN KLEIN: ALL RIGHT. WE HAVE PUBLIC  
24 COMMENT AT THE MICROPHONE. AND THEN WE'LL LOOK FOR  
25 ADDITIONAL BOARD COMMENTS, THEN ASK WHETHER THERE WILL

1 BE A MOTION, AND WHETHER THAT MOTION WILL ADDRESS THE  
2 ITEMS THAT BERNIE HAS AUGMENTED HIS REPORT WITH AS  
3 REFERENCED HERE TODAY.

4 WE HAVE HELP ON THE WAY. THE STEM CELL  
5 MAGICIAN IS ON THE WAY. TRANSCRIPTIONIST, IF SHE  
6 SPEAKS LOUDLY, CAN WE TRY THAT? NO. SHE HAS  
7 HEADPHONES ON.

8 MS. SAMUELSON: I HAVE A QUESTION IN THE  
9 INTERIM.

10 CHAIRMAN KLEIN: PERHAPS, JOAN -- WHY DON'T  
11 YOU GO TO THE CENTER CONSOLE AND SPEAK NEXT TO DR. LO.

12 MS. SMITH-CROWLEY: I'M SHANNON  
13 SMITH-CROWLEY, AND I'M REPRESENTING THE AMERICAN  
14 COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, DISTRICT 9,  
15 WHICH REPRESENTS CALIFORNIA OB/GYN'S AND THE AMERICAN  
16 SOCIETY FOR REPRODUCTIVE MEDICINE. I'M A LOBBYIST, AND  
17 I WORKED LAST YEAR ON SENATE BILL 18 WITH SENATOR  
18 ORTIZ. SO I WAS UP TO MY EYEBALLS IN THIS ISSUE, AND I  
19 CONGRATULATE YOU ON THIS DOCUMENT. THIS WAS VERY  
20 DIFFICULT WORK, AND YOU DID A SUPERB JOB.

21 I DO WANT TO YOU LET YOU KNOW, AS YOU  
22 PROBABLY ARE NOT FOLKS THAT ARE STEEPED IN THE  
23 REPRODUCTIVE RIGHTS COMMUNITY, SO THERE MAY BE SOME  
24 SENSITIVITIES THAT YOU MAY NOT BE AWARE OF.

25 THE HEIGHTENED INFORMED CONSENT IS A GREAT

1     IDEA.  THE IDEA OF GIVING MUCH MORE SPECIFIC DETAIL A  
2     AS TO THE RISKS INVOLVED, AND THERE IS RISK, IT'S  
3     LIMITED, BUT THERE IS AND THAT SHOULD BE KNOWN,  
4     ESPECIALLY WHEN THERE'S NO BENEFIT TO THAT DIRECT  
5     PATIENT.  HOWEVER, AND I'M TRYING TO KEEP MY KNEE FROM  
6     KIND OF COMING UP AND BEING KNEE JERK.  THE  
7     DELIBERATIVE PERIOD, AND WHEN YOU'RE TALKING ABOUT THE  
8     REPRODUCTIVE RIGHTS FIELD, AND YOU'RE TALKING ABOUT  
9     OTHER STATES' WAITING PERIODS FOR ABORTIONS, TALKING  
10    ABOUT WAITING PERIODS FOR PARENTS TO BE NOTIFIED, IT IS  
11    UNDERMINING, IF THIS GOES THROUGH, WHAT WE HAVE BEEN  
12    WORKING FOR FOR DECADES TO PUT A SPECIFIC REQUIREMENT  
13    THAT THERE IS A DELIBERATION PERIOD.

14               I BELIEVE THAT YOU'RE ALREADY GETTING TO THAT  
15    WITH GOING THROUGH THE INFORMED CONSENT PROCESS.  AND  
16    ESPECIALLY I LOVE WHAT YOU ARE DOING IN TERMS OF THE  
17    TESTING OF THE COMPETENCY.  IN CALIFORNIA, WITH ALL OF  
18    THE LANGUAGES AND DIFFERENT CULTURES THAT WE HAVE, THAT  
19    IS PARTICULARLY IMPORTANT.  WE'VE GOT CONCERNS ABOUT  
20    LANGUAGE ACCESS IN TERMS OF PEOPLE GETTING THE  
21    MATERIALS IN THE CORRECT LANGUAGE.  SO WE THINK THAT IF  
22    YOU'RE DOING THE TESTING, THAT THERE'S NOT QUITE THE  
23    SAME NEED FOR THE WAITING PERIOD.

24               I'VE HAD BRIEF DISCUSSIONS WITH TRADITIONAL  
25    REPRODUCTIVE RIGHTS ORGANIZATIONS THAT HAVE REPRESENTED



1 WOMEN FOR DECADES, SUCH AS PLANNED PARENTHOOD AND  
2 CALIFORNIA NATIONAL ORGANIZATION FOR WOMEN. AND THEY  
3 WILL RESPOND WHEN THE REGULATIONS GO OUT FOR COMMENT  
4 AND HAVE THE SAME CONCERNS. I DO THINK THAT IF YOU  
5 WANTED TO TAKE ACTION TODAY, THAT YOU COULD DELETE THE  
6 PARAGRAPH THAT -- MOST OF THE PARAGRAPHS ABOUT TALKING  
7 ABOUT THE ADEQUATE TIME PERIOD AND JUST REALLY LET THE  
8 REST FLOW FROM THERE. THANK YOU.

9 CHAIRMAN KLEIN: THANK YOU VERY MUCH. THE  
10 NEXT SPEAKER. I THINK THE MIC MIGHT BE WORKING.

11 MS. THOMPSON: I'M CHARIS THOMPSON FROM UC  
12 BERKELEY. I'D LIKE TO ADD MY VOICE TO THE CHORUS OF  
13 PEOPLE SAYING WHAT AN EXTRAORDINARY DOCUMENT THIS IS.  
14 AND I'D ALSO LIKE TO SAY THAT, IN GENERAL, OVER THE  
15 LAST FEW MONTHS, MY SENSE OF CIRM AND THE ICOC AND THE  
16 MEMBERS OF THE PUBLIC WHO HAVE BEEN ENGAGED IN THIS  
17 ENDEAVOR, IT'S ACTUALLY BEEN LIFE CHANGING FOR ME AS AN  
18 EXAMPLE OF GOVERNANCE IN SCIENCE AND BIOMEDICINE.  
19 THANK YOU FOR THAT.

20 I WOULD LIKE TO ADD A COUPLE OF COMMENTS TO  
21 THIS DOCUMENT AS SOMEBODY WHO'S UNDERGONE EGG  
22 EXTRACTION. TWO MAJOR CONCERNS OF PATIENTS, ACTUALLY  
23 LONG-TERM HEALTHCARE ONES, WHICH ARE SUBSEQUENT  
24 INFERTILITY AND RESULTS OF OVARIAN HYPERSTIMULATION  
25 DOWN THE LINE SUCH AS CANCER. THERE ARE EASY WAYS TO

1     RULE OUT BOTH OF THOSE OR TO MORE OR LESS RULE THEM  
2     OUT.  ONE IS TO REQUIRE THAT AN EGG DONOR HAVE ALREADY  
3     ONE LIVING CHILD.  YOU CAN MAKE EXCEPTIONS FOR PEOPLE  
4     IN CASES OF AUTOLOGOUS DONATION OR WHO HAVE EVIDENCE  
5     THAT THEY DO NOT WISH TO HAVE REPRODUCTION IN THE  
6     FUTURE SUCH AS TUBAL LIGATION, BUT THAT IN GENERAL  
7     SOMEBODY WHO DONATES EGGS SHOULD HAVE A LIVING CHILD.  
8             AND A SECOND -- AND THAT WOULD FIT WITH YOUR  
9     PRINCIPLE OF THE REPRODUCTIVE -- OPTIMIZING  
10    REPRODUCTIVE OUTCOME.  
11            AND THE SECOND CONDITION WOULD BE TO PUSH  
12    TOWARDS DEVELOPING PROTOCOLS AND INCLUDING TRACKING  
13    REGULATIONS FOR OVARIAN TISSUE BIOPSY WHICH WOULD RULE  
14    OUT THE GONADOTROPIN PHASE OF OOCYTE EXTRACTION.  SO  
15    GIVEN THAT THERE HAVE BEEN SO MANY PUBLICATIONS IN THE  
16    LAST YEAR COMING OUT OF THE ASSISTED REPRODUCTIVE  
17    TECHNOLOGIES FIELD ON SUCCESSES IN GETTING OVARIAN  
18    TISSUE, FREEZING IT, USING IT WHEN YOU NEED IT, SO THAT  
19    SCIENTISTS COULD USE IT WHEN THEY NEED IT.  THERE ARE  
20    MANY OOCYTES LIKE THAT THAT CAN BE DERIVED IN THAT  
21    MANNER.  SOMEHOW THAT BE WRITTEN INTO THIS AND BE  
22    OFFERED TO PATIENTS AS AN OPTION THAT WOULDN'T REQUIRE  
23    THAT THEY UNDERGO OVARIAN HYPERSTIMULATION.  THANK YOU.  
24            CHAIRMAN KLEIN:  THANK YOU VERY MUCH.  
25            MR. REYNOLDS:  JESSE REYNOLDS OF THE CENTER

1 FOR GENETICS AND SOCIETY. I'D LIKE TO EXTEND MY THANKS  
2 TO CO-CHAIRS DR. LO AND MS. LANSING FOR LEADING THE  
3 PROCESS THAT HAS BECOME QUITE OPEN AND INCLUSIVE. AND  
4 I EXTEND THOSE THANKS TO DR. HALL AND GEOFF LOMAX FOR  
5 RESPONDING SO QUICKLY TO A LETTER OF CONCERN ABOUT THE  
6 DISCREPANCIES THAT WERE MENTIONED THAT I SENT OUT ONLY  
7 TWO DAYS AGO. SO THANKS TO THEM.

8 BUT I DON'T KNOW IF I CAN UNDERSTATE THE  
9 IMPORTANCE OF THESE MEDICAL AND ETHICAL STANDARDS.  
10 WHAT'S AT STAKE IS NOT ONLY THE HEALTH AND WELL-BEING  
11 OF THOSE WHO PROVIDE MATERIALS FOR THE RESEARCH TO GO  
12 FORWARD, BUT ALSO THE MOMENTUM OF STEM CELL RESEARCH  
13 ITSELF. OF COURSE, PUBLIC SUPPORT WOULD BE VASTLY  
14 UNDERMINED BY THINGS SUCH AS THE FIRST ATTEMPTS AT  
15 REPRODUCTIVE CLONING WITH THE PRODUCTS OF THE RESEARCH,  
16 OR WITH SIMILAR ABUSES OF THE WOMEN WHO PROVIDE EGGS  
17 FOR RESEARCH AS WE SAW IN SOUTH KOREA.

18 JUST A WORD ABOUT THAT. IN THAT CASE THIS  
19 HASN'T BEEN WIDELY REPORTED IN THE AMERICAN MEDIA. TEN  
20 TIMES AS MANY EGGS WERE USED AS WERE INITIALLY  
21 REPORTED. TWENTY PERCENT OF THE WOMEN WHO PROVIDED THE  
22 EGGS FOR RESEARCH ENDED UP BEING HOSPITALIZED. AND  
23 THESE ABUSES WERE UNCOVERED BY INVESTIGATIVE  
24 JOURNALISTS AND, BY EXTENSION, MEMBERS OF THE PUBLIC.

25 SO ON THESE STANDARDS THEMSELVES, THE DETAILS

1 HAVE COME A LONG WAY. WHAT DR. LO PRESENTED, A LOT OF  
2 THAT HAS COME A LONG WAY, AND THERE'S SOME THAT STILL  
3 HAVE ROOM FOR IMPROVEMENT. BUT ALL DUE RESPECT TO THE  
4 MEMBERS OF THE STANDARDS WORKING GROUP, THE CORE OF  
5 THIS REMAINS FLAWED. THE CORE IS THE OVERSIGHT  
6 MECHANISM. THREE LAYERS ARE NEEDED, AND EACH ONE AS IT  
7 STANDS ARE INADEQUATE.

8 AND, FIRST, YES, APPROVAL BY LOCAL BOARDS IS  
9 APPROPRIATE. THE COMPOSITION AND INSTITUTIONAL  
10 AFFILIATION OF THESE LOCAL BOARDS WILL LEAVE THEM TO BE  
11 SYMPATHETIC WITH THE SCIENCE GOING FORWARD AS RAPIDLY  
12 AS POSSIBLE.

13 SECOND, THE DECISIONS OF THESE LOCAL  
14 COMMITTEES NEED TO BE OVERSEEN BY AN AGENCY THAT IS  
15 INDEPENDENT OF THE CIRM AND THESE LOCAL COMMITTEES  
16 THEMSELVES.

17 AND THIRD, THERE NEEDS TO BE PUBLIC  
18 INFORMATION AVAILABLE ABOUT THE DECISIONS OF THESE  
19 LOCAL BOARDS, ABOUT THE RECORDKEEPING IN SECTION II,  
20 BUT ALSO ADDITIONAL INFORMATION SUCH AS THE  
21 DEMOGRAPHICS OF THE WOMEN WHO PROVIDE THE EGGS FOR  
22 RESEARCH.

23 SO WE BELIEVE THAT UNDER THIS PROPOSAL, THAT  
24 WE FEAR -- WE THINK OUR FEARS ARE WARRANTED, THAT WOMEN  
25 WILL BE HARMED WHO PROVIDE EGGS FOR THIS EVENTUALLY,

1 AND THAT THERE'S LIKELY TO BE ABUSES OF THESE POWERFUL  
2 NEW TECHNOLOGIES. AND I URGE YOU TO RECONSIDER THIS.  
3 THANK YOU.

4 MR. REED: I HAVE TWO THOUGHTS. FIRST, ON  
5 THE IDEA THAT THE DONOR SHOULD LOOK INTO THE FUTURE AND  
6 CHOOSE WHICH TYPES OF EXPERIMENTATION HER TISSUES MIGHT  
7 BE USED ON I SEE AS A COMPLICATION AND POTENTIAL  
8 LAWSUITS DOWN THE ROAD. I WOULD SUGGEST THAT INSTEAD  
9 IT BE APPROACHED MORE IN THE MANNER OF THIS IS A  
10 DONATION YOU'RE NOBLY GIVING, AND IT WILL NOT BE  
11 POSSIBLE TO FOLLOW IT UP. NO TELLING WHAT CAN HAPPEN.  
12 THESE ARE THE THINGS THAT COULD HAPPEN AND LIST  
13 POSSIBILITIES THAT WE KNOW OF AND SAY IS IT ALL RIGHT  
14 FOR YOU TO DONATE AND THEN DECIDE.

15 SECONDLY, I WOULD SUGGEST THAT WE FOLLOW THE  
16 ENGLISH EXAMPLE AND GIVE AN ACTUAL TEST ON THE  
17 INFORMATION THAT INFORMED CONSENT REQUIRES. IF WE GAVE  
18 AN ACTUAL TEST, WHICH THEY WOULD HAVE TO PASS, THEN  
19 THEY COULD NEVER EVER SAY THEY DID NOT UNDERSTAND  
20 BECAUSE WE WOULD HAVE DOCUMENTED PROOF THAT THEY DID.

21 CHAIRMAN KLEIN: THANK YOU VERY MUCH. WE  
22 ALSO HAVE A CALLED-IN COMMENT FROM DR. JACK LEWIN OF  
23 THE CALIFORNIA MEDICAL ASSOCIATION. AS THEIR EXECUTIVE  
24 DIRECTOR, I AM WRITING TO EXPRESS MY STRONG SUPPORT FOR  
25 THE DRAFT MEDICAL AND ETHICAL STANDARDS TO GUIDE THE

1     IMPORTANT RESEARCH FUNDED BY THE CALIFORNIA INSTITUTE  
2     FOR REGENERATIVE MEDICINE. CALIFORNIA IS AGAIN LEADING  
3     THE WAY BY BECOMING THE FIRST STATE IN THE NATION TO  
4     CREATE ENFORCEABLE REGULATIONS, THE FOCUS ON THE  
5     COMPLEX SCIENTIFIC, MEDICAL, AND ETHICAL ISSUES THAT  
6     ARISE FROM THE STEM CELL RESEARCH WITH A STARTING POINT  
7     OF THE NATIONAL ACADEMY OF SCIENCES GUIDELINES THAT  
8     REPRESENT A NATIONAL CONSENSUS FOR RESEARCH PRINCIPLES.  
9     THE REGULATIONS BEING CONSIDERED BY THE ICOC HAVE A  
10    FIRM FOUNDATION.

11               THE PROPOSED REGULATIONS ALSO REAFFIRM SOLID  
12    SAFEGUARDS BUILT INTO THE CALIFORNIA STEM CELL RESEARCH  
13    AND CURES ACT SUCH AS PROHIBITION FOR HUMAN PRODUCTIVE  
14    CLONING.

15               THERE'S ADDITIONAL LANGUAGE THERE. MY  
16    UNDERSTANDING IS THAT THIS WILL BE A FAXED COPY THAT WE  
17    WILL BE ABLE TO LATER POST FOR HIS FULL COMMENTS.

18               WITH THE PUBLIC COMMENTS HAVING BEEN MADE,  
19    DR. LO OR SHERRY LANSING, WOULD YOU LIKE TO COMMENT ON  
20    THE WAITING PERIOD NOTIFICATION QUESTION RAISED BY THE  
21    PUBLIC OR ANY OTHER ITEM RAISED BY THE PUBLIC?

22               DR. LO: I'D LIKE TO AND THEN ASK SHERRY TO  
23    COMMENT AS WELL. FIRST, I WANT TO THANK THE PUBLIC FOR  
24    THEIR COMMENTS. I THINK THIS IS JUST THE BEGINNING OF  
25    WHAT WE ANTICIPATE WILL BE A VERY RICH DIALOGUE, THAT

1 THE WHOLE POINT OF THIS ADMINISTRATIVE LAW PROCEDURE IS  
2 TO OFFER THE PUBLIC A PERIOD OF TIME TO MAKE COMMENTS,  
3 TO GO BACK AND FORTH WITH US TO ENSURE WE UNDERSTAND  
4 THEIR CONCERNS AND THEIR THOUGHTS AND FOR US TO  
5 RESPOND. I THINK IT'S INCUMBENT ON US AS AN SWG TO  
6 TAKE THESE COMMENTS AND TO THINK THEM THROUGH AND TO  
7 RESPOND.

8 JUST SOME OF THE COMMENTS THAT WERE MADE,  
9 FIRST WITH REGARD TO THE WAITING PERIOD, WE TRIED TO BE  
10 SENSITIVE TO THAT AND WE AVOIDED THE TERM "WAITING  
11 PERIOD," BUT WE UNDERSTAND THAT THE CONCEPT MAY STILL  
12 BE OF CONCERN. IT MAY WELL BE THAT IT IS NOT  
13 NECESSARY, GIVEN THE NATURE OF SORT OF THE ASCERTAINING  
14 IF THE WOMAN UNDERSTOOD, AND I THINK THAT'S SOMETHING  
15 WE'LL NEED TO THINK ABOUT, AND WE'RE CERTAINLY OPEN TO  
16 REVISING, PARTICULARLY IF THERE'S ANY LANGUAGE THAT CAN  
17 ADDRESS THAT.

18 WITH REGARD TO THE SECOND SET OF COMMENTS  
19 FROM PROFESSOR THOMPSON, SHE RIGHTLY POINTS OUT THAT  
20 THERE ARE OTHER TECHNIQUES THAT WOULD NOT INVOLVE  
21 HORMONAL STIMULATION, AND THAT ALSO IT WOULD BE  
22 IMPORTANT TO PAY ATTENTION TO TRYING TO IDENTIFY DONORS  
23 WHERE FUTURE REPRODUCTIVE SUCCESS WOULD NOT BE AN  
24 ISSUE. I THINK THAT'S SOMETHING, AGAIN, WE WOULD  
25 WELCOME SPECIFIC LANGUAGE ON HOW TO DO THAT AND

1       SOMETHING WE WILL VERY MUCH CONSIDER.

2               I WANT TO ADD THAT, AND I GUESS ZACH COULD  
3       SAY MORE, THAT THERE IS A SYMPOSIUM PLANNED THAT THE  
4       INSTITUTE OF MEDICINE AND NATIONAL ACADEMY OF SCIENCES  
5       WILL BE DIRECTING THAT CIRM IS HELPING TO FUND ALONG  
6       WITH OTHER FOUNDATIONS TO CONDUCT A WORKSHOP TO BRING  
7       THE BEST AVAILABLE SCIENTIFIC INFORMATION ON THIS ISSUE  
8       OF THE RISKS OF OOCYTE DONATION. AND WE THINK THAT IT  
9       WOULD BE VERY IMPORTANT TO HAVE THAT MEETING TO BUILD  
10      ON IT IN TERMS OF INCORPORATING THE VERY BEST AND  
11      LATEST SCIENCE ON WHAT THOSE RISKS ARE AND WHAT STEPS  
12      MIGHT BE TAKEN TO MINIMIZE THEM. AND WE THINK, AGAIN,  
13      WE'RE COMMITTED TO MINIMIZING RISKS, AND WE WANT TO  
14      MAKE SURE WE DO IT IN A WAY THAT IS IN ACCORD WITH THE  
15      SOUNDEST SCIENCE.

16             WITH THE THIRD SET OF COMMENTS REGARDING THE  
17      NEED FOR ADDITIONAL OVERSIGHT, AGAIN, I THINK THAT  
18      NEEDS TO BE IN THE CONTEXT OF THE COMPLIANCE  
19      REGULATIONS THAT YOU ARE GOING TO HEAR ABOUT. I THINK  
20      THAT THERE'S A BALANCE BETWEEN HAVING TOO LITTLE --  
21      THERE'S A RISK IN HAVING TOO LITTLE OVERSIGHT AND  
22      THERE'S ALSO A RISK IN HAVING TOO MUCH OVERSIGHT. I  
23      THINK THERE ARE MODELS THAT HAVE WORKED IN TERMS OF  
24      HAVING AN ADDITIONAL LAYER OF OVERSIGHT ABOVE AND  
25      BEYOND WHAT THE INSTITUTIONS DO AND WHAT THE PEER



1 REVIEW PROCESS DOES, AND THERE ARE PLUSES AND MINUSES  
2 TO THAT.

3 I WAS PRIVILEGED TO SERVE ON THE NIH  
4 RECOMBINANT DNA ADVISORY COMMITTEE FOR A THREE-YEAR  
5 TERM THAT IS MANDATED TO REVIEW ALL GENE TRANSFER  
6 RESEARCH. IT'S AN EXTRA LAYER OF REVIEW ABOVE  
7 SCIENTIFIC REVIEW, FDA REVIEW, AND IRB REVIEW. WE  
8 THOUGHT WE MADE A LOT OF IMPORTANT CONTRIBUTIONS TO  
9 STRENGTHEN OUR PROTOCOLS, BUT THERE ARE ALSO A LOT OF  
10 RESEARCHERS WHO THOUGHT IT WAS AN UNNECESSARY AND  
11 DUPLICATIVE PROCESS. SO I THINK WE NEED TO BE OPEN TO  
12 WAYS TO MAKE THE OVERSIGHT PROCESS STRONGER AND MORE  
13 THOUGHTFUL, AND WE ALSO WANT TO AVOID OVERDOING IT.

14 AGAIN, I WOULD WELCOME SPECIFIC SUGGESTIONS  
15 AS TO HOW TO STRENGTHEN WHAT WE HAVE, AND PARTICULARLY  
16 THE ISSUE OF WHAT WE CAN DO TO MAKE THE LOCAL OVERSIGHT  
17 PROCESS WORK AS WELL AS POSSIBLE. AGAIN, JUST TO -- I  
18 THINK INSTITUTIONS WILL VARY. AT OUR INSTITUTION WE'VE  
19 HAD A SCRO COMMITTEE NOW FOR A NUMBER OF YEARS. AND  
20 OUR REVIEWS ARE REALLY TOUGH. YOU CAN ASK THE  
21 RESEARCHER WHO JUST WENT THROUGH A THREE-HOUR REVIEW  
22 THREE WEEKS AGO. IT WAS NOT A RUBBER STAMP, AND WE  
23 ASKED TOUGH SCIENCE QUESTIONS, A LOT OF TOUGH ETHICS  
24 QUESTIONS, BUT I THINK IT'S IMPORTANT THAT THAT  
25 INSTITUTIONAL PROCESS BE AS ROBUST AS POSSIBLE. AND WE

1 UNDERSTAND THERE HAVE BEEN CASES OF SOME INSTITUTIONS  
2 NOT JUST ALLEGEDLY, BUT PROBABLY ALSO IN REALITY NOT  
3 LIVING UP TO THEIR TASK.

4 THE FINAL TWO COMMENTS ABOUT ACTUALLY GIVING  
5 AN EXAMINATION, AGAIN, WE WANT TO BUILD IN FLEXIBILITY  
6 BECAUSE WHAT WE WANT TO TEST IS THE CORE THINGS, AND WE  
7 WANT TO TEST IT IN A WAY THAT REALLY CONTRIBUTES TO AN  
8 INFORMATIONAL DIALOGUE. AND WE REALLY THINK THAT WE  
9 DON'T KNOW HOW TO DO THAT RIGHT NOW AND WE WANT TO  
10 LEAVE IT OPEN TO THE IRB'S AND THE RESEARCHERS TO  
11 FIGURE OUT HOW TO DO IT BETTER. I THINK WITH  
12 EXPERIENCE THEY'LL COME UP WITH BETTER WAYS.

13 IN TERMS OF GETTING BLANKET CONSENT FOR  
14 EVERYTHING, WE EXPRESSLY SAY THAT RESEARCHERS MAY  
15 CHOOSE TO DO THAT, AND WE ACCEPT THIS NOTION OF SAYING  
16 THESE ARE ALL THE KINDS OF THINGS THAT MIGHT BE DONE  
17 WITH CELLS, PLUS THINGS WE CAN'T THINK OF, BUT WE DON'T  
18 WANT TO SAY ONLY THOSE CELLS BECAUSE WE WERE GIVEN  
19 EXAMPLES OF RESEARCH PROJECTS, FOR EXAMPLE, WITH CELLS  
20 OBTAINED WITH PGBD, BIOPSIES THAT MAY, IN FACT, INVOLVE  
21 CELLS THAT HAVE MUTATIONS FOR SEVERE GENETIC DISEASES  
22 WHERE IT MAY ONLY BE USED FOR VERY RESTRICTIVE  
23 PURPOSES. AND THE PERSON WHO DONATES THOSE CELLS MAY  
24 NOT WANT TO SIGN ON FOR ALL FUTURE USES, BUT MAY JUST  
25 WANT CERTAIN RESEARCH USES THAT A RESEARCHER ON THAT

1 PARTICULAR DISEASE ENTITY WANTS TO STUDY. SO WE WANTED  
2 TO BUILD IN THAT KIND OF FLEXIBILITY, BUT WE DO WELCOME  
3 THESE COMMENTS. AS I SAY, WE THINK THIS IS ONLY THE  
4 FIRST OF MANY COMMENTS THAT WE REALLY DO LOOK FORWARD  
5 TO AND LOOK FORWARD TO COMING BACK TO YOU AT THE ICOC  
6 TO PRESENT OUR REASONED RESPONSE TO THOSE COMMENTS.

7 CHAIRMAN KLEIN: CO-CHAIRMAN LANSING, WOULD  
8 YOU LIKE TO MAKE ANY COMMENTS?

9 MS. LANSING: I THINK BERNIE REALLY COVERED  
10 ALL OF THE THINGS THAT I WAS GOING TO SAY WITH THE  
11 EXCEPTION OF POSSIBLY ONE. AGAIN, I THINK THIS SHOWS  
12 YOU HOW HELPFUL THE PUBLIC HAS BEEN TO US THROUGHOUT  
13 THIS PROCESS, AND SOME OF YOU HAVE BEEN WITH US SINCE  
14 THE VERY, VERY FIRST MEETING, AND WE REALLY, REALLY  
15 WELCOME THAT.

16 I THINK IN REGARD TO THE WAITING PERIOD, AND  
17 I UNDERSTAND BOTH SIDES OF IT, I GUESS WE WANT TO BE  
18 THE MOST STRINGENT IN THE BEGINNING. AND, AGAIN, I SAY  
19 WE CAN EXAMINE THIS ISSUE OVER AND OVER AGAIN. BUT I  
20 THINK OUR THINKING WAS TO GO ABOVE AND BEYOND ANYTHING,  
21 AND WE CAN ALWAYS PULL THINGS BACK AS WE SEE HOW THE  
22 PROCESS WORKS.

23 ALSO, IN RESPONSE TO CHOOSING PEOPLE WHO HAVE  
24 COMPLETED THEIR REPRODUCTIVE NEEDS, I WOULD HATE TO  
25 ELIMINATE PEOPLE WHO CHOOSE NOT TO HAVE CHILDREN. AND

1 SO TO ME I THINK IT IS EXTREMELY IMPORTANT THAT WE  
2 REALIZE THAT THAT'S A VALID CHOICE, AND THAT WE ALSO  
3 SAY TO OURSELVES THAT'S PART OF INFORMED CONSENT. AND  
4 THAT CONTINUES TO BE SOMETHING THAT I THINK WE CAN  
5 EXAMINE.

6 IN JUST A SECOND, THE OVERSIGHT, IT'S A VERY  
7 FINE LINE BETWEEN GETTING IT SO COMPLICATED AND SO  
8 BUREAUCRATIC THAT NOTHING WILL GET DONE. SO, AGAIN, I  
9 JUST CONCLUDE BY SAYING HOW MUCH BERNIE AND I AND  
10 EVERYONE ON THE COMMITTEE, ALL THE PEOPLE WHO ARE HERE  
11 TODAY WELCOME THE PUBLIC COMMENTS, THE COMMENTS FROM  
12 THE LEGISLATURE, AND THE COMMENTS FROM OUR FELLOW ICOC  
13 BOARD MEMBERS. BUT, AGAIN, THIS IS SO IMPORTANT, ALL  
14 OF US KNOW THAT AS THE SCIENCE CHANGES, AND IT WILL  
15 CHANGE, AS WE BECOME MORE INFORMED, WE ARE GOING TO  
16 MAKE CHANGES IN THIS DOCUMENT, NOT JUST IN THE NEAR  
17 FUTURE, BUT IN THE YEARS TO COME, AND WE ARE COMMITTED  
18 TO DOING THAT, AND OUR GROUP IS COMMITTED TO CONTINUING  
19 TO MEET.

20 CHAIRMAN KLEIN: YES, DR. PIZZO. AND PLEASE  
21 RECALL WE HAVE SOME OTHER CRITICAL ITEMS TO GO THROUGH  
22 TODAY. WE ARE GOING TO LOSE A QUORUM IN A WHILE. THIS  
23 IS EXTRAORDINARILY GOOD DISCUSSION. WE WILL HAVE THE  
24 APA PUBLIC HEARINGS. WE WILL BRING IT BACK TO THE  
25 BOARD FOR FINAL ACTION. AND IN THAT CONTEXT, WHAT HAS

1 TO BE SAID TODAY, WE SHOULD CERTAINLY SAY TODAY. TO  
2 THE EXTENT THAT WE CAN, AS REFERENCED EARLIER, REALLY  
3 RESPECT THAT PROCESS AND THE SCIENTIFIC CONFERENCE  
4 WHICH WILL GIVE US TREMENDOUS KNOWLEDGE AND  
5 INFORMATION, LET US BE AWARE OF THAT.

6 DR. PIZZO: CERTAINLY UNDERSTANDING THAT THIS  
7 IS A WORK IN PROGRESS AS HAS BEEN ARTICULATED, I  
8 RECOMMEND THAT THE ICOC VOTE APPROVAL OF THIS  
9 PARTICULAR PROPOSAL WITH THE REVISIONS THAT HAVE BEEN  
10 DEVELOPED AS WELL.

11 DR. THAL: I SECOND IT.

12 CHAIRMAN KLEIN: THE MOTION IS MADE AND  
13 SECONDED. WE CAN STILL HAVE COMMENTS.

14 MS. SAMUELSON: FIRST, LET ME SAY THAT I'M  
15 DEEPLY GRATEFUL TO THIS WORKING GROUP AND ITS LEADERS.  
16 CLEARLY THE A TEAM WAS BROUGHT TO THIS, AND I FEEL  
17 FULLY INFORMED AND SUPPORTIVE AND WILL VOTE IN FAVOR OF  
18 IT. I'VE GOT A COUPLE OF CLARIFYING QUESTIONS.

19 I GUESS I'D JUST BE CURIOUS, AND YOU REALLY  
20 SPOKE TO THIS QUITE A BIT, SO I HAVE A GREAT SENSE OF  
21 IT. BUT IF YOU COULD POSITION WHERE THESE STANDARDS  
22 SIT IN THE SPECTRUM FROM VERY, VERY RESTRICTIVE AND  
23 CAREFUL DOWN TO THE NTH DEGREE THAT THERE WON'T BE ANY  
24 ETHICAL OVERSIGHT TO TRYING TO MAKE AVAILABLE THE TOOLS  
25 FOR THE RESEARCH AS AGGRESSIVELY AS POSSIBLE. I THINK

1     THAT'S THE SPECTRUM.  BECAUSE I THINK IT'S IMPORTANT TO  
2     REMEMBER THAT UTTERLY STRICT RULES AREN'T PER SE THE  
3     GOAL, RIGHT?

4             MS. LANSING:  BUT TO START, WE SAID WHEN WE  
5     STARTED OUR GROUP, THAT WE WERE NOT GOING TO  
6     RUBBER-STAMP THE NATIONAL ACADEMY OF SCIENCE.  WE WERE  
7     GOING TO MAKE IT BETTER.  WE WERE GOING TO MAKE IT  
8     STRICTER.  WE'VE ALL SEEN EXAMPLES OF WHAT CAN HAPPEN  
9     WHEN THE RULES AREN'T THERE.  SO I THINK THIS IS THE  
10    BEGINNING, DO YOU KNOW, AND I THINK IF WE LEANED OVERLY  
11    ONE WAY IN THE FIRST PHASE, THAT WOULD NOT BE SO BAD,  
12    AND WE COULD START TO PULL BACK ON IT.

13            MS. SAMUELSON:  AS LONG AS THERE'S OVERSIGHT.

14            MS. LANSING:  I WANT TO SAY REALLY CLEARLY  
15    THESE ARE NOT CUMBERSOME.  THEY WILL NOT STOP ANYTHING.  
16    THESE ARE NOT TOO RESTRICTIVE.  THEY WILL NOT PREVENT  
17    US FROM DOING OUR WORK.

18            MS. SAMUELSON:  I GUESS THAT'S THE LAST PIECE  
19    OF THE QUESTION.  IN THE EGG DONATION CASE, FOR  
20    EXAMPLE, HOW CONFIDENT ARE YOU THAT THERE WILL BE A  
21    SUFFICIENT SUPPLY FOR WHATEVER IS CURRENTLY PROJECTED?

22            DR. LO:  IF I COULD RESPOND TO YOUR QUESTION  
23    AND ACTUALLY ADD TO WHAT SHERRY SAID.  IF YOU THINK OF  
24    A SPECTRUM FROM NO OVERSIGHT AT ALL TO LAX OVERSIGHT AT  
25    THIS EXTREME, AND SO MUCH OVERSIGHT THAT THE RESEARCH

1     WON'T GET DONE, WE'RE CLEARLY NOWHERE NEAR THAT  
2     EXTREME. WHERE WE TRIED TO POSITION OURSELF IS TO SAY  
3     WE'RE DOING EVERYTHING THAT IS SENSIBLE THAT IS ALREADY  
4     REQUIRED AND WE'RE PUSHING BEYOND THAT, BUT WE'RE  
5     PUSHING BEYOND IT IN A WAY THAT IS NOT GOING TO SLOW  
6     DOWN THE RESEARCH.

7             ONE OF THE MEMBERS OF OUR COMMITTEE, ANN  
8     KIESSLING, ACTUALLY HAS EXTENSIVE EXPERIENCE RECRUITING  
9     WOMEN TO DONATE OOCYTES SOLELY FOR RESEARCH. WHAT  
10    WE'RE PROPOSING IS VERY CONSISTENT WITH WHAT SHE AND  
11    HER GROUP HAVE ACTUALLY WORKED OUT IN PRACTICE. THEY  
12    HAVE NO SHORTAGE OF WOMEN THAT ARE WANTING TO DONATE  
13    FOR RESEARCH. THEIR EXPERIENCE IS IT'S A VERY  
14    DIFFERENT GROUP DEMOGRAPHICALLY THAN THE GROUP OF WOMEN  
15    WHO WISH TO DONATE OOCYTES TO WOMEN IN IVF THAT YOU CAN  
16    SEE, FOR EXAMPLE, IN STANFORD.

17            SO WE WERE VERY MINDFUL OF THE POSSIBILITY  
18    THAT OUR OVERSIGHT COULD STIFLE THE RESEARCH. AND WE  
19    THINK WE'RE WELL SORT OF AWAY FROM THAT.

20            AND IF I COULD FOLLOW ON WHAT SHERRY SAID, I  
21    THINK IT'S A REALLY IMPORTANT POINT. AT THIS STAGE,  
22    PARTICULARLY GIVEN THE VERY NATURAL PUBLIC SENSITIVITY  
23    IN THE WAKE OF WHAT HAPPENED IN KOREA SURROUNDING  
24    OOCYTE DONATION, AS ONE OF OUR SPEAKERS SAID, WHERE  
25    THERE WAS A QUESTION, WE WANTED TO ERR ON THE SIDE OF

1 BEING A LITTLE BIT TOO STRICT AS OPPOSED TO BEING A  
2 LITTLE TOO LAX. AGAIN, THIS IS EXPERIENCED BASED.  
3 THIS IS WHAT BRITAIN HAS DONE WITH THE HEFA. THEY  
4 STARTED OUT BEING MUCH MORE RESTRICTIVE; AND AS THEY  
5 GOT MORE EXPERIENCE AND THE PUBLIC TRUSTED THEM AND THE  
6 PEOPLE COULD SEE IT COULD BE DONE, THEY GRADUALLY, BUT  
7 THEY DIDN'T DO IT IN A WAY THAT CUT SHORT THE WORK TO  
8 BE DONE. THAT'S WHAT, I THINK, WE'RE TRYING TO PROPOSE  
9 HERE.

10 CHAIRMAN KLEIN: THANK YOU VERY MUCH.  
11 ADDITIONAL QUESTIONS?

12 DR. PRIETO: I WOULD JUST LIKE TO RESPOND  
13 ALSO TO WHAT JOAN SAID. I THINK PARTICULARLY AT THIS  
14 EARLY STAGE, IT'S IMPORTANT THAT WE DO BUILD TRUST AND  
15 BUILD CONFIDENCE, SO IF WE SOMETIMES ERRED ON THAT  
16 SIDE, I THINK THAT THAT WAS A VALID CHOICE TO MAKE.  
17 AND WE DID DISCUSS THIS AT GREAT LENGTH, AND I'D  
18 ENCOURAGE ANY OF YOU WHO ARE INTERESTED IN THESE  
19 QUESTIONS TO PLEASE LOOK AT SOME OF THE TRANSCRIPTS OF  
20 THE WORKING GROUP DISCUSSION BECAUSE THERE'S A LOT OF  
21 THOUGHTFUL COMMENT THERE.

22 CHAIRMAN KLEIN: I CAN'T SEE THE HAND. BOARD  
23 MEMBER FEIT.

24 MS. FEIT: JUST TO COMMENT, AGAIN, ON JOAN'S  
25 QUESTION. WE HAD ALSO ON THE COMMITTEE PEOPLE LIKE



1 DR. ANN KIESSLING AND ROBERT TAYLOR, WHO ARE WELL  
2 EXPERIENCED IN EGG COLLECTION AND REALLY SUPPORTED THE  
3 DIRECTION WE WERE GOING IN. SO WE FELT WE HAD EXPERT  
4 ADVICE IN THIS AREA.

5 CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS IT  
6 THE SENSE OF THE BOARD AT THIS TIME. WE HAVE TAKEN  
7 PRIOR BOARD TESTIMONY, BUT WILL RECOGNIZE AN  
8 ADDITIONAL, ONE ADDITIONAL MEMBER OF THE PUBLIC'S  
9 COMMENT. AND THEN IF IT'S THE SENSE OF THE BOARD, WE  
10 WILL GO TO A VOTE.

11 MS. AURITI: THANK YOU. ELLEN AURITI FROM  
12 THE UNIVERSITY OF CALIFORNIA. I JUST WANTED TO OFFER A  
13 COMMENT ON THE NEW PROVISION THAT WAS JUST ADDED ABOUT  
14 COVERING THE COSTS OF HUMAN SUBJECT INJURY. ONE OF OUR  
15 CAMPUSES RECENTLY POINTED OUT TO US THAT THERE MAY BE A  
16 CONFLICT IN THE REQUIREMENT THAT GRANTEES COVER THE  
17 SUBJECT INJURY. THE UNIVERSITY OF CALIFORNIA'S POLICY  
18 WITH RESPECT TO INDUSTRY-SPONSORED TRIALS OR  
19 INDUSTRY-SPONSORED RESEARCH IS THAT A COMMERCIAL  
20 SPONSOR WOULD SHARE OR ASSUME THE COST OF INJURY. AND  
21 WE WANT TO MAKE SURE THAT NOTHING THAT'S ENACTED IN THE  
22 CIRM REGULATIONS WOULD PRECLUDE US FROM REQUIRING AN  
23 INDUSTRY SPONSOR TO PAY THEIR SHARE IN A CASE WHERE  
24 THEY'RE INVOLVED IN FUNDING.

25 DR. LO: GOOD POINT.

1                   CHAIRMAN KLEIN:  THANK YOU.

2                   MR. GOLDBERG:  MAKE A MOTION FOR APPROVAL.

3                   CHAIRMAN KLEIN:  THE MOTION IS ON THE FLOOR.

4  YOU'RE CALLING THE QUESTION; IS THAT CORRECT?

5                   MR. GOLDBERG:  YES.

6                   CHAIRMAN KLEIN:  ALL IN FAVOR.  OPPOSED?

7  OKAY.  THANK YOU.  AND, AGAIN, THIS IS A TREMENDOUS

8  EFFORT BY THE STANDARDS COMMITTEE.

9                   (APPLAUSE.)

10                  CHAIRMAN KLEIN:  WE NEED TO PROCEED

11  IMMEDIATELY THROUGH SEVERAL ITEMS.  WITH DR. BIRGENEAU

12  LEAVING, WE ARE NOT LOSING OUR QUORUM BECAUSE WE HAVE

13  AN ALTERNATE HERE.  THANK YOU VERY MUCH.  IT IS

14  IMPORTANT FOR US TO NOW MOVE TO ITEM 10.

15                  DR. HALL, WOULD YOU LIKE TO ADDRESS ITEM 10

16  ON THE AGENDA?  IT'S THE POLICY FOR REMOVAL OF WORKING

17  GROUP MEMBERS.

18                  DR. HALL:  SCOTT TOCHER IS GOING TO TAKE CARE

19  OF THAT.

20                  CHAIRMAN KLEIN:  OKAY.  SCOTT.

21                  MR. TOCHER:  GOOD AFTERNOON, CHAIRMAN, BOARD

22  MEMBERS, AND PRESIDENT HALL.  HERE ON ITEM 10,

23  PROPOSITION 71 ESTABLISHES BASIC RULES GOVERNING THE

24  APPOINTMENT OF WORKING GROUP MEMBERS.  HOWEVER, THE ACT

25  IS SILENT AS TO THE CIRCUMSTANCES AND PROCEDURES FOR

1 THEIR REMOVAL. HOWEVER, THE ACT ALLOWS THE ICOC TO  
2 ESTABLISH GUIDELINES FOR THE OPERATIONS OF THESE  
3 WORKING GROUPS. AND TO THAT END, THE FOLLOWING  
4 PROPOSAL IS DESIGNED TO ADDRESS THE ISSUE OF THE  
5 REMOVAL OF WORKING GROUP MEMBERS FOR CAUSE.

6 SECTION I DESCRIBES THE CIRCUMSTANCES FOR  
7 REMOVAL FOR CAUSE OF WORKING GROUP MEMBERS. THESE WERE  
8 INSPIRED BY PROVISIONS IN OTHER STATE LAWS AND POLICIES  
9 GOVERNING OTHER LOCAL AND STATE BODIES. AND IT IS  
10 REALLY, I THINK, IF YOU LOOK AT IT, SORT OF A  
11 COMMON-SENSE LIST OF CIRCUMSTANCES THAT WOULD ALLOW  
12 REMOVAL. THEY ARE DELINEATED IN SECTION I, NOS. 1  
13 THROUGH 7. AND THEY INCLUDE INTENTIONAL OR GROSSLY  
14 NEGLIGENT VIOLATIONS OF THE CONFLICT OF INTEREST  
15 POLICY, A SERIES OF UNEXCUSED ABSENCES, VIOLATION OF  
16 PROFESSIONAL MEDICAL OR ETHICAL STANDARDS, PROFESSIONAL  
17 EMPLOYMENT THAT WOULD RESULT IN AN UNAVOIDABLE  
18 CONFLICT; AND, FINALLY, A CATCHALL FOR FELONIES OR  
19 OTHER SERIOUS MISCONDUCT.

20 THE SECOND PORTION DESCRIBES THE INITIAL  
21 PROCEDURES FOR SUSPENSION OF THE WORKING GROUP MEMBER,  
22 AND THAT IS ACCOMPLISHED WHEN THE PRESIDENT OF CIRM  
23 GIVES WRITTEN NOTICE OF THE SUSPENSION AND THE GROUNDS  
24 FOR DOING SO THAT ARE DELINEATED ABOVE IN SECTION I.  
25 THAT SUSPENSION REMAINS IN EFFECT UNTIL ANY ONE OF

1 THREE CIRCUMSTANCES. ONE, IT IS TERMINATED BY THE  
2 PRESIDENT; SECOND, THERE IS A RESIGNATION OF THE  
3 MEMBER; OR, 3, UPON CONSIDERATION OF THE ICOC.

4 SECTION III IS SORT OF A RELIEF VALVE WHICH  
5 ALLOWS THE CIRM PRESIDENT OR THE WORKING GROUP CHAIR TO  
6 ALLOW FOR EXCUSED ABSENCES UP TO SIX MONTHS FOR GOOD  
7 CAUSE.

8 FINALLY, STEP -- SECTION IV OF THE POLICY  
9 DESCRIBES THE CONCLUSION OF THE REMOVAL PROCESS, WHICH  
10 IS ACCOMPLISHED WHEN THE PRESIDENT NOTIFIES THE ICOC,  
11 WHICH THEN CONDUCTS A HEARING AT ITS MEETING WHERE THE  
12 WORKING GROUP MEMBER CAN ADDRESS THE BOARD EITHER IN  
13 PERSON OR IN WRITING, AFTER WHICH TIME A VOTE IS TAKEN  
14 BY THE BOARD.

15 CHAIRMAN KLEIN: THANK YOU VERY MUCH, SCOTT.  
16 QUESTIONS FROM THE BOARD MEMBERS? BUT FIRST A  
17 CLARIFICATION FROM COUNSEL. WE'RE ADDRESSING HERE  
18 WORKING GROUP MEMBERS WHO WOULDN'T OTHERWISE BE COVERED  
19 BY THE ICOC CONFLICT PROVISIONS AND OTHER PROVISIONS,  
20 SO IT'S NON-ICOC MEMBERS; IS THAT CORRECT?

21 MR. HARRISON: THAT'S CORRECT. THIS POLICY  
22 APPLIES ONLY TO NON-ICOC MEMBERS IN THE WORKING GROUPS.

23 CHAIRMAN KLEIN: THANK YOU. BOARD QUESTIONS?

24 DR. STEWARD: SO AS THEY'RE WRITTEN, THE  
25 POLICY SEEMS WELL-THOUGHT OUT AND FINE. I RAISE THE

1 QUESTION, THOUGH. IT'S MY UNDERSTANDING THAT IT'S THE  
2 ICOC THAT APPOINTS MEMBERS OF THE WORKING GROUP AND,  
3 THEREFORE, I'M CURIOUS WHY IT IS THE PRESIDENT OF CIRM  
4 WHO'S LISTED IN SEVERAL POINTS THERE AS MAKING  
5 DECISIONS. I'M A LITTLE CONCERNED ABOUT THAT IN TERMS  
6 OF THE DUTIES OF THE ICOC.

7 MR. TOCHER: I THINK THAT THE -- FIRST OF  
8 ALL, BECAUSE THE PRESIDENT OF CIRM OVERSEES THE  
9 DAY-TO-DAY OPERATIONS AND BECAUSE CIRM -- BECAUSE THE  
10 ICOC BOARD IS SORT OF AN OVERSIGHT OF THAT FUNCTION,  
11 THAT THE INITIAL SORT OF PROCEDURE SEEMED PROPER TO  
12 VEST IT WITH THE DAY-TO-DAY OPERATIONS OF THE WORKING  
13 GROUPS AND WITH CIRM TO SORT OF TAKE AN INITIAL TAKE ON  
14 THE CIRCUMSTANCES THAT MIGHT GIVE RISE TO THE  
15 SUSPENSION OR ULTIMATE REMOVAL.

16 DR. HALL: LET ME JUST SAY THAT PART OF IT IS  
17 THE PROCEDURE FOR SUSPENSION. WITH THE ICOC MEETING  
18 EVERY TWO MONTHS, WE SOMETIMES NEED TO MEET MORE  
19 QUICKLY THAN THAT. AND IF THERE IS A REAL PROBLEM, WE  
20 NEED TO BE VERY RESPONSIVE SO IT. SO IT'S MEANT TO BE  
21 WORDED SO THAT WE SUSPEND, AND THEN WE BRING IT TO THE  
22 ICOC FOR CONSIDERATION EITHER TO VOID THE SUSPENSION OR  
23 CONSIDER THE PERMANENT REMOVAL. AND ALSO IT'S OUR DUTY  
24 ACTUALLY, I BELIEVE, TO BRING TO YOUR ATTENTION ANY  
25 MISCONDUCT THAT WE BELIEVE -- OR REASON FOR

1 DISQUALIFICATION THAT WE BELIEVE GOES ON.

2 SO I'M MEANT TO ACT AS YOUR DAY-TO-DAY AGENT  
3 AND BRING THESE MATTERS TO YOUR ATTENTION, BUT NOT TO  
4 SUPERSEDE YOUR AUTHORITY.

5 CHAIRMAN KLEIN: SO VERY CLEARLY, THE  
6 PRESIDENT IS ACTING TO SUSPEND AND MAKE SURE WE HAVE  
7 IMMEDIATE ACTION, BUT IT'S THE ICOC WHICH WILL REMOVE  
8 IF APPROPRIATE. ADDITIONAL QUESTIONS?

9 DR. JENNINGS: ONE QUICK QUESTION IS ON NO. 5  
10 ON THE FIRST PAGE. ARE THERE CONCERNS ABOUT -- IT SAYS  
11 INSTITUTION LOCATED. ARE WE CONCERNED ABOUT BRANCH  
12 OFFICES OF COMPANIES, OR PROBLEMS OF MERGERS, SO THE  
13 HOME OFFICE CAN CHANGE WHERE THE INDIVIDUAL DOESN'T  
14 CHANGE AT ALL?

15 DR. HALL: THESE ARE UNIVERSITY SCIENTISTS.  
16 ON OUR COMMITTEE WE HAVE ONE PERSON FROM A BIOTECH  
17 COMPANY, BUT THE THING WE'RE MOST CONCERNED ABOUT AT  
18 THIS POINT ARE NOT THEIR COMPANY AFFILIATIONS, BUT  
19 WE'VE HAD AT LEAST ONE CASE IN WHICH A MEMBER OF THE  
20 GRANTS WORKING GROUP WAS IN NEGOTIATION WITH A  
21 CALIFORNIA INSTITUTION, AND WE SAID WE THINK YOU NEED  
22 TO STEP ASIDE. THEY AGREED AND THEY DID.

23 DR. JENNINGS: IT'S A POSSIBILITY, BUT NOT A  
24 SERIOUS ONE.

25 DR. HALL: I TOLD THEM IN THE VERY FIRST

1     PHONE CALLS I MADE TO THEM IF YOU ENTER INTO SERIOUS  
2     NEGOTIATIONS, DEFINED AS A SERIOUS VISIT TO TALK ABOUT  
3     A JOB, THEN YOU NEED TO LET US KNOW BECAUSE YOU'RE IN  
4     POTENTIAL CONFLICT OF INTEREST AT THAT POINT.

5             CHAIRMAN KLEIN:  THANK YOU VERY MUCH.  IS  
6     THERE COMMENTS FROM THE PUBLIC, AND THEN WE'LL GET DR.  
7     TINA NOVA AS AN ADDITIONAL COMMENT FROM THE BOARD.

8             MS. SAMUELSON:  AND I HAVE A QUESTION.

9             CHAIRMAN KLEIN:  NO COMMENTS FROM THE PUBLIC.

10            DR. NOVA:  I JUST WANTED TO CLARIFY, MR.  
11     CHAIRMAN, THAT THIS POLICY WAS REVIEWED BY THE  
12     GOVERNANCE COMMITTEE IN THEIR MEETING, BUT WE DID NOT  
13     HAVE A QUORUM.  AND SO WE WERE ONLY ABLE TO GET A SENSE  
14     OF THE COMMITTEE ON THIS MATTER, BUT IT WAS THE SENSE  
15     FROM THE COMMITTEE THAT WE DO MOVE FORWARD WITH THE  
16     REMOVAL POLICY TO THE ICOC TODAY.

17            CHAIRMAN KLEIN:  THANK YOU VERY MUCH FOR YOUR  
18     REPORT, DR. NOVA.  ADDITIONAL COMMENTS AND QUESTIONS?

19            MS. SAMUELSON:  MY QUESTION IS UNDER NUMBER  
20     PARAGRAPH 3, UNEXCUSED ABSENCE, WHAT WOULD CONSTITUTE  
21     AN APPROPRIATE EXCUSE?  WHAT'S THE PROCEDURE FOR THAT?

22            DR. HALL:  WELL, ALMOST ALWAYS WE HAVE PEOPLE  
23     WHO HAVE CONFLICTS, CAN'T COME, THEY'VE AGREED TO SPEAK  
24     AT A SCIENTIFIC MEETING, THEY'RE TEACHING.  WE SAY  
25     THAT'S FINE.  IF THEY JUST DON'T SHOW UP AND THIS

1       HAPPENS REPEATEDLY, THEN WE DETECT A CERTAIN LACK OF  
2       INTEREST AND WANT TO BE ABLE TO BE FREE TO ACT  
3       ACCORDINGLY.

4               CHAIRMAN KLEIN:   ALL RIGHT.   IS THERE A  
5       MOTION?

6               DR. NOVA:   SO MOVED.

7               CHAIRMAN KLEIN:   MOTION IS BY DR. NOVA.  
8       SECOND?

9               DR. PIZZO:   SECOND.

10              CHAIRMAN KLEIN:   SECOND BY DR. PIZZO.  
11       ADDITIONAL DISCUSSION?   ALL IN FAVOR.   OPPOSED?   THANK  
12       YOU VERY MUCH.   GREAT PRESENTATION.

13              WE ARE GOING TO GO ON AT THIS POINT TO ITEM  
14       13.   IT HAS ARISEN DURING OUR BRIDGE FINANCING EFFORT  
15       THAT INDIVIDUALS MAY BE INTERESTED IN A NAMING  
16       OPPORTUNITY TO BENEFIT THE CIRM BASED UPON A PREFERENCE  
17       TO GIVE A GRANT RATHER THAN BUYING THE BOND  
18       ANTICIPATION NOTES.   THERE ARE OBVIOUS VERY SUBSTANTIAL  
19       BENEFITS TO THE PEOPLE OF CALIFORNIA OF A GRANT.

20              ON THE SCREEN YOU WILL SEE THAT AT OUR AUGUST  
21       31ST GOVERNANCE COMMITTEE MEETING, WE FIRST DISCUSSED  
22       THIS POTENTIAL FOR NAMING OPPORTUNITIES.   IT WAS  
23       RECOMMENDED THAT THE EXECUTIVE COMMITTEE, THAT IS, THE  
24       CHAIRMAN, THE VICE CHAIRMAN, AND THE PRESIDENT, MAKE A  
25       DETERMINATION FOR A NAMING OPPORTUNITY FOR BAN



1 PURCHASES TO FUND THE TRAINING GRANT AND OR THE SEED  
2 MONEY INNOVATION GRANT PROGRAM OF 10 MILLION OR MORE.

3 NOW, LET ME EXPLAIN THAT. IF THE PERSON MADE  
4 VERY CLEAR AS AN INTENTION THAT AFTER ONE YEAR THEY  
5 WOULD EITHER MAKE IT AN OUTRIGHT GRANT OR DONATE THEIR  
6 BOND ANTICIPATION NOTES, SO THAT WE WOULD PERMANENTLY  
7 HAVE THE BENEFIT OF AT LEAST \$10 MILLION. THERE WOULD  
8 BE A PERMANENT NAMING OF THE FELLOWSHIP PROGRAM, THE  
9 CIRM SCHOLARS PROGRAM. IT WAS DISCUSSED IN THE  
10 COMMITTEE THAT THIS WOULD BE SUBJECT TO CONSIDERATION  
11 HERE AT THE BOARD AND APPROVAL BY THE BOARD.

12 AS A PART OF THIS MOTION, THE PROGRAM WOULD  
13 BE DELEGATED TO THE EXECUTIVE COMMITTEE FOR  
14 IMPLEMENTATION TO BE BROUGHT BACK TO THIS BOARD FOR  
15 ACCEPTANCE OF THE FINAL DETERMINATION AND ACCEPTANCE OF  
16 THE GRANT. SO THIS IS AN IMPLEMENTATION STEP, BUT YOU  
17 WILL SEE THE FINAL APPROVAL COMING BACK TO YOU.

18 IT IS IMPORTANT TO NOTICE THESE THREE  
19 ELEMENTS AS SUMMARIZED IN THE PROPOSED RESOLUTION IF  
20 IT'S THE SENSE OF THIS COMMITTEE. NOTICE, AGAIN, THE  
21 ACTUAL GRANT OR GIFT WILL BE BROUGHT BACK TO THE BOARD  
22 AT A FUTURE MEETING FOR FINAL APPROVAL. IT IS A  
23 SIGNIFICANT ITEM TO REALIZE THAT THE GIFT OF FUNDS  
24 COULD BE USED FOR ANY OF THE PURPOSES OF THE CIRM,  
25 INCLUDING THE RAMP-UP THAT DR. HALL REFERENCED AND

1 DR. ARLENE CHIU HAS ADDRESSED BEFORE IN THE SCIENTIFIC  
2 STAFF TO GIVE US THE INTERNAL CAPACITY TO REACH THE  
3 LEVEL OF SCIENTIFIC STAFF NECESSARY TO PROCESS OUR NEXT  
4 ROUND OF GRANTS, WHICH WE MAY HAVE SUBSTANTIALLY AND  
5 HOPEFULLY SUBSTANTIALLY AT GREATER VOLUME.

6 IS THERE DISCUSSION BY THE BOARD ON THIS  
7 ITEM? SHERRY LANSING AND THEN DR. FRIEDMAN.

8 MS. LANSING: I JUST WANT TO REMIND THOSE OF  
9 US IN THE GOVERNANCE COMMITTEE, AND THEN TO KIND OF  
10 EXPLAIN WHY WE CAME TO THIS. AND I THINK WE ALL FELT  
11 THAT IF WE WERE SO LUCKY THAT SOMEONE WISHED TO GIVE US  
12 DURING THIS TIME OF LAWSUITS \$10 MILLION WITH NO  
13 RESTRICTIONS ON IT, THAT THEY COULD HAVE THEIR NAME IN  
14 PERPETUITY. AND I THINK I FEEL THAT THAT'S A  
15 REASONABLE THING TO SAY. \$10 MILLION IS A GREAT DEAL  
16 OF MONEY. IT COULD BE USED FOR A GREAT DEAL OF GRANTS.  
17 WE KNOW THAT WE'RE TRYING TO GET BAN'S. THOSE ARE  
18 GOING TO BE REIMBURSED.

19 THIS IS SOMETHING THAT'S AN OUTRIGHT GIFT.  
20 AND I THINK IT WOULD BE UNREASONABLE TO NOT HAVE AN  
21 OUTRIGHT GIFT GO WITH A NAMING OPPORTUNITY.

22 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND  
23 DR. FRIEDMAN.

24 DR. FRIEDMAN: I TOO WOULD LIKE TO SPEAK IN  
25 SUPPORT OF THIS FOR A SLIGHTLY DIFFERENT REASON, WHICH

1 IS, NOT ONLY AT THIS MOMENT WHEN WE NEED MONEY TO DO  
2 THE RESEARCH, BUT AT ANY TIME. I THINK THE FUNDAMENTAL  
3 QUESTION IS WHAT'S IN THIS FOR THE CITIZENS OF THE  
4 STATE? AND ANY WAY IN WHICH WE CAN LEVERAGE. PEOPLE  
5 TALK ABOUT PUBLIC-PRIVATE PARTNERSHIPS. THIS IS A REAL  
6 DEMONSTRATION OF THAT. WITH THE UNDERSTANDING THAT  
7 THERE ARE NO RESTRICTIONS, IT CAN BE USED AT THE  
8 DISCRETION CONSISTENT WITH OUR STRATEGIC PLAN AND OUR  
9 PROCESSES, I THINK THIS IS A PERFECTLY LEGITIMATE  
10 THING.

11 ONE CAN IMAGINE DIFFICULTIES THAT CERTAIN  
12 INDIVIDUALS WHO MIGHT BE UNSAVORY CHARACTERS OR  
13 SOMETHING, YOU MIGHT NOT WANT TO HAVE A NAME ASSOCIATED  
14 WITH IT. IT COMES BACK TO THIS GROUP FOR A DECISION,  
15 AND WE CAN MAKE THAT DECISION AT THE TIME. AND SO I  
16 THINK THIS IS A PERFECTLY REASONABLE THING TO DO AND  
17 WOULD BE STRONGLY SUPPORTIVE. I DON'T WANT TO GET INTO  
18 THE DETAILS. WE MAY WANT TO HAVE AN INDIVIDUAL OR A  
19 FOUNDATION'S NAME HYPHENATED WITH CIRM SO THAT THE  
20 PUBLIC KNOWS THIS IS A COLLABORATION, BUT I'LL LEAVE  
21 THAT TO OTHER PEOPLE TO DISCUSS WHEN WE ACTUALLY HAVE A  
22 CANDIDATE TO FOCUS ON.

23 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

24 DR. PIZZO: SUPPORTING THE IDEA AS HAS BEEN  
25 PUT FORWARD. THE ONLY CAVEAT I WOULD OFFER IS I DON'T

1 KNOW THAT WE COULD CALL THIS SOMETHING IN PERPETUITY  
2 LIKE AN ENDOWMENT BECAUSE, FIRST OF ALL, ARE THE FUNDS  
3 GOING TO BE EXPENDABLE OR PUT INTO ENDOWMENT? THAT'S  
4 NO. 1. NO. 2 IS WHAT HAPPENS IF TEN YEARS FROM NOW OR  
5 AT SOME POINT IN THE FUTURE CIRM GOES OUT OF BUSINESS  
6 BECAUSE THERE AREN'T ANY FUNDS? SO WE JUST HAVE TO BE  
7 CLEAR WITH DONORS ABOUT WHAT TO EXPECT. IT'S DIFFERENT  
8 FROM --

9 MS. LANSING: ISN'T THIS SUPPOSED TO BE USED  
10 FOR SCIENCE?

11 CHAIRMAN KLEIN: THE POINT HERE, IN ANSWER TO  
12 THE QUESTION, IS THAT THE FUNDS CAN BE USED FOR ANY  
13 PROPER USE VOTED BY THIS BOARD IN PUBLIC SESSION AS  
14 RECOMMENDED BY THE PRESIDENT. THE KEY HERE IS IN  
15 PERPETUITY IN THIS SENSE WILL COME BACK AS LIMITED BY  
16 THE EXISTENCE OF THE INSTITUTION AND THE SPECIFIC  
17 FELLOWSHIP PROGRAM.

18 DR. PIZZO: I OFFER THAT ONLY IN THE SPIRIT  
19 OF JUST BEING SURE WE'RE CLEAR WITH POTENTIAL DONORS.

20 DR. FRIEDMAN: GOOD POINT.

21 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I  
22 WOULD LIKE TO HAVE DR. CLAIRE POMEROY, AND IT'S BEEN  
23 SUGGESTED TO ME ALSO TO BRING TO THE PUBLIC'S ATTENTION  
24 THAT LECTURESHIPS AND ENDOWED PROFESSORSHIPS ARE NAMED  
25 IN THE UC SYSTEM AS WELL AS BUILDINGS TO GIVE SOMEONE A

1 REFERENCE POINT FOR THIS WITHIN STATE OF CALIFORNIA'S  
2 SCIENTIFIC AND EDUCATIONAL SYSTEM TODAY. DR. POMEROY  
3 AND THEN JEFF SHEEHY.

4 DR. POMEROY: SO IS THE PROPOSAL IN FRONT OF  
5 US JUST ABOUT THE PROCESS FOR A NAMING OPPORTUNITY FOR  
6 TRAINING GRANTS RIGHT NOW? WE'RE NOT TALKING ABOUT  
7 DONATIONS FOR OTHER PURPOSES TODAY?

8 CHAIRMAN KLEIN: NO. THIS IS FOCUSED ONLY ON  
9 THE FELLOWSHIP PROGRAM.

10 DR. POMEROY: SO THIS WOULD BE EXCLUSIVELY  
11 MONEY THAT WENT OUT IN GRANTS AS OPPOSED TO  
12 ADMINISTRATIVE COSTS?

13 CHAIRMAN KLEIN: NO. THESE FUNDS COULD COME  
14 TO CIRM TO BE USED FOR PURPOSES APPROVED BY THIS BOARD  
15 IN PUBLIC MEETINGS, BUT THE INTENT IS NOT TO HAVE IT  
16 TIED TO FUNDING THE TRAINING GRANTS. IF WE HAVE  
17 SUFFICIENT MONEY TO FUND THAT USE, WE MIGHT, FOR  
18 EXAMPLE, UP TO THE BOARD'S APPROVAL, USE IT TO MEET, AS  
19 DR. HALL SAID, THE NEED TO RAMP UP THE SCIENTIFIC STAFF  
20 TO HANDLE THE NEXT ROUND OF GRANT PROCESSING.

21 MS. LANSING: WE'LL GET TO APPROVE IT EACH  
22 TIME.

23 CHAIRMAN KLEIN: THE NAME IS ONLY  
24 ADDRESSING -- THE NAME IS ONLY TO BE ATTACHED TO THE  
25 FELLOWSHIP PROGRAM.

1 DR. HALL: I RECOMMEND THAT, ACTUALLY URGE  
2 YOU THAT YOU JUST CONSIDER THE PROCESS RIGHT NOW  
3 WITHOUT GETTING INTO HYPOTHETICAL DETAILS. ANY  
4 SPECIFIC PROPOSAL WILL BE BROUGHT TO THIS GROUP. AT  
5 THAT POINT YOU CAN DISCUSS WHATEVER RESTRICTIONS MIGHT  
6 OR MIGHT NOT BE APPROPRIATE. I THINK THE KEY POINT NOW  
7 IS JUST TO AGREE TO THE PROCESS.

8 CHAIRMAN KLEIN: ANY ADDITIONAL POINTS?

9 MR. SHEEHY: I WAS JUST GOING TO MAKE A QUICK  
10 POINT. THERE'S AMPLE PRECEDENT FOR THIS. I THINK IT'S  
11 A GREAT IDEA. WITHIN THE NIH THERE'S THE FOGERTY  
12 GRANTS, WHICH ARE TRAINING GRANTS, WHICH ARE  
13 ADMINISTERED BY THE NIH, SO WE'RE NOT DOING ANYTHING  
14 THAT'S UNUSUAL BY ANY MEANS.

15 CHAIRMAN KLEIN: THANK YOU. DR. MEYER.

16 DR. MEYER: ALSO A MEMBER OF THE GOVERNANCE  
17 COMMITTEE THAT VOTED ON THIS, AND IT WAS JUST  
18 OVERWHELMING. ONE THING THAT COMES TO MIND IS, WELL,  
19 WOW, TEN MILLION BUCKS. WHERE ARE WE GOING TO GET THAT  
20 FROM THAT ONE PERSON? I'VE BEEN WORKING WITH BOB, AND  
21 I'M CONVINCED THAT THROUGH HIS EFFORTS, THIS IS NOT PIE  
22 IN SKY. THIS IS IMMINENTLY DOABLE, SO WHAT WE'RE  
23 VOTING FOR HERE IS SOMETHING THAT'S VERY TANGIBLE, VERY  
24 CONCRETE, AND THE IDEA THAT IT'S A DONATION, NOT A BAN,  
25 THE IDEA THAT IT WILL BE FUNGIBLE, AND CAN BE PUT WHERE

1 WE NEED IT NOW IS A BIG SELLING POINT.

2 AND, OF COURSE, THE MOST IMPORTANT THING IS  
3 THE MOMENTUM THAT IT WOULD GIVE US, AS HAS BEEN POINTED  
4 OUT, THAT, HEY, LOOK. WE HAVE PEOPLE WHO ARE WILLING  
5 TO PUT THEIR MONEY WHERE THEIR MOUTH IS AND KEEP THIS  
6 THING GOING.

7 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ANY  
8 ADDITIONAL COMMENTS? ANY ADDITIONAL PUBLIC COMMENTS?

9 MR. REYNOLDS: JESSE REYNOLDS FROM THE CENTER  
10 FOR GENETICS AND SOCIETY. THERE'S A SCENARIO IN WHICH  
11 THIS COULD OPEN UP THE DOOR TO A CERTAIN TYPE OF REAL  
12 OR PERCEIVED CONFLICT OF INTEREST. I UNDERSTAND THAT  
13 WHAT'S ON THE TABLE HERE RIGHT NOW IS JUST A MATTER OF  
14 PROCEDURE.

15 WHAT I WOULD RECOMMEND PERHAPS IS THAT IN THE  
16 NEAR TERM, IF THIS BECOMES MORE LIKELY, THAT EXPLICIT  
17 CRITERIA ABOUT INSTITUTIONS OR INDIVIDUALS THAT WOULD  
18 BE PROHIBITED FROM PURSUING SUCH A NAMING OPPORTUNITY  
19 BE SPELLED OUT. A GENERAL POSSIBILITY WOULD BE AN  
20 INSTITUTION OR A CORPORATION THAT HAS AN INTEREST IN  
21 HOW THESE GRANTS ARE LATER OR OTHER GRANTS ARE LATER  
22 DELIVERED. I THINK THAT SOMETHING THAT COULD BE MORE  
23 CLEARLY PERCEIVED BY THE PUBLIC IN A NEGATIVE LIGHT  
24 WOULD BE SOMETHING LIKE THE GERON FELLOWSHIP PROGRAM.  
25 IT LOOKS A LOT DIFFERENT THAN THE DOLBY FELLOWSHIP

1 PROGRAM. THERE'S A BIG DIFFERENCE IN PERCEPTION THERE  
2 AND IN REALITY. THANK YOU.

3 CHAIRMAN KLEIN: I THINK I'M IN HEATED  
4 AGREEMENT WITH YOU, AND WE ARE VERY SENSITIVE TO THAT  
5 AND WILL CONSIDER IT BY THIS BOARD WHEN IT COMES BACK  
6 FOR FINAL ADOPTION.

7 IS THERE A DESIRE TO CALL THE QUESTION?

8 DR. PIZZO: SO MOVED.

9 CHAIRMAN KLEIN: ALL IN FAVOR. OPPOSED? THE  
10 MEASURE PASSES.

11 WE'RE GOING TO GO NEXT TO ITEM 14, AND DR.  
12 HALL.

13 DR. HALL: I'D ACTUALLY -- I NEED YOUR HELP  
14 ON TWO ITEMS, ONE FAIRLY SHORT, I HOPE, AND THE OTHER A  
15 LITTLE MORE LENGTHY. SO IF I COULD TAKE ITEM NO. 15  
16 FIRST AND THEN GO TO ITEM NO. 14.

17 I HAVE TALKED ON A NUMBER OF OCCASIONS ABOUT  
18 OUR INTEREST IN HAVING A MEETING ON ASSESSMENT OF  
19 MEDICAL RISK TO EGG DONORS, AND THE INTENT OF THIS  
20 MEETING IS TO FOCUS ON THE SCIENCE AND ASK WHAT DO WE  
21 KNOW BASED ON AVAILABLE DATA? WHAT DO WE NEED TO KNOW?  
22 AND ARE THERE PRACTICES THAT WE COULD UNDERTAKE OR  
23 RECOMMEND THAT WOULD MITIGATE OR REDUCE RISK FOR EGG  
24 DONORS?

25 WE HAVE IN OUR DISCUSSIONS EVOKED INTEREST



1 FROM THE SOCIETY FOR GYNECOLOGIC INVESTIGATION, WHICH,  
2 AS I INDICATED BEFORE, IS THE LEADING SCIENTIFIC  
3 SOCIETY IN GYNECOLOGIC RESEARCH, A VERY PRESTIGIOUS  
4 GROUP. THEY WISH TO CO-SPONSOR WITH US, AND WE  
5 TOGETHER WOULD THEN INVITE THE INSTITUTE OF MEDICINE  
6 AND THE NATIONAL ACADEMY OF LIFE SCIENCES BOARD TO  
7 ORGANIZE AND RUN THE MEETING, WHICH WOULD MEET IN  
8 CALIFORNIA.

9 WE WOULD ASK THEM TO DO IT. THEY WOULD  
10 CHOOSE AN ORGANIZING COMMITTEE. THE ORGANIZING  
11 COMMITTEE WOULD CHOOSE THE SPEAKERS. SO THE MEETING  
12 WOULD NOT BE RUN BY US IN ANY SENSE, BUT WOULD BE DONE  
13 AT OUR REQUEST, SO THIS WOULD GIVE US, WE HOPE, THE  
14 VERY BEST INFORMATION UNDER THE MOST OBJECTIVE POSSIBLE  
15 CIRCUMSTANCES. WE HAVE GREAT INTEREST, I THINK, IN  
16 HAVING THIS INFORMATION. IT IS PART OF OUR OBLIGATION,  
17 IN TERMS OF WHAT WE'VE JUST BEEN TALKING ABOUT TO WOMEN  
18 WHO DONATE EGGS TO UNDERSTAND AS BEST AS WE CAN WHAT  
19 THE RISKS ARE AND WHAT PRACTICES THERE ARE.

20 FURTHERMORE, AS FAR AS WE CAN TELL, THERE HAS  
21 NOT BEEN A NATIONAL MEETING ON THIS TOPIC, AND WE THINK  
22 THIS WILL BE OF NATIONAL AND EVEN INTERNATIONAL  
23 IMPORTANCE. WE THINK IT IS IMPORTANT. AND,  
24 FURTHERMORE, WE THINK WE SHOULD GET TO IT AS QUICKLY AS  
25 POSSIBLE.

1                   NOW, SO I WOULD LIKE TO REQUEST YOUR  
2   AUTHORITY TO COMMIT, WHEN THE MONEY BECOMES AVAILABLE,  
3   AND I'LL COME TO THAT IN A MOMENT, BUT TO COMMIT UP TO  
4   \$200,000 TO HAVE SUCH A MEETING. THE MEETING WOULD BE  
5   IN CALIFORNIA. THE INSTITUTE OF MEDICINE AND THE  
6   NATIONAL ACADEMIES' LIFE SCIENCES BOARD, THEIR SERVICES  
7   DO NOT COME CHEAPLY, SO WE WOULD WORK WITH THEM TO HAVE  
8   THE MEETING IN AS ECONOMICAL A WAY AS POSSIBLE, AND I  
9   SIMPLY POINT TO OUR PREVIOUS EXPERIENCE IN WHICH WE  
10  BUDGETED FOR OUR PREVIOUS MEETING \$215,000, AND WE  
11  ENDED UP ACTUALLY DOING IT FOR HOW MUCH, ARLENE? 145  
12  OR SOMETHING, 130.

13                  BUT I WANT THE FREEDOM TO BE ABLE TO DO THIS  
14  MEETING WITHOUT FURTHER DELAY AND TO GET IT GOING.  
15  INSTITUTE OF MEDICINE WILL NOT DO ANYTHING UNTIL WE  
16  SIGN A CONTRACT WITH THEM. SO I ASK FOR YOUR APPROVAL,  
17  IF WE CAN RAISE A \$200,000 GIFT THAT WOULD GO TO THIS,  
18  FOR YOUR APPROVAL TO GO AHEAD AND COMMIT THAT MONEY  
19  TOWARD A CONTRACT WITH THE INSTITUTE OF MEDICINE AND  
20  THE NATIONAL ACADEMIES TO BEGIN WORK ON THIS MEETING.  
21  IF WE WERE TO START TODAY, IT WOULD PROBABLY TAKE -- WE  
22  COULD DO IT SOMETIME IN MAY, BUT AS WE WAIT LONGER,  
23  THAT DATE GETS PUT OFF. I'M OPTIMISTIC ABOUT US BEING  
24  ABLE TO RAISE THAT MONEY, AND SO THAT'S WHY I COME TO  
25  YOU IN ADVANCE TO ASK FOR THAT AUTHORITY.

1 DR. FRIEDMAN: I SO MOVE.

2 (MULTIPLE SECONDS.)

3 CHAIRMAN KLEIN: YES. ANY BOARD COMMENTS? I

4 THINK THIS IS AN OUTSTANDING EXAMPLE OF THE LEADERSHIP

5 THAT WE CAN PROVIDE, AND IN THE FACT THAT WE'RE DOING

6 IT IN A TIME PERIOD THAT'S CONCURRENT WITH THE

7 ADMINISTRATIVE PROCEDURES ACT WITH THE MEDICAL AND

8 ETHICAL STANDARDS IS HIGHLY RELEVANT TO OUR DUE

9 DILIGENCE AND THE CONTRIBUTION OF THE PUBLIC AND THE

10 PROFESSIONAL SOCIETIES TO THIS DEBATE AND THE STANDARDS

11 THAT WE MOVE FORWARD WITH.

12 ANY ADDITIONAL BOARD POINTS? ANY POINTS FROM

13 THE AUDIENCE? NO POINTS FROM THE AUDIENCE.

14 CALL FOR THE QUESTION. ALL IN FAVOR.

15 OPPOSED? MOTION PASSES. DR. HALL.

16 DR. HALL: OKAY. I'D NOW LIKE TO ASK YOUR

17 PERMISSION ALSO TO COMMIT A SLIGHTLY LARGER AMOUNT OF

18 MONEY. AND I WOULD ASK -- I WILL NEED YOUR APPROVAL TO

19 DO THIS, AND SO I WOULD ASK YOUR HELP IN MAINTAINING A

20 QUORUM AS LONG AS POSSIBLE. I'LL TRY TO MOVE THROUGH

21 THIS FAIR QUICKLY, BUT JUST TO LET YOU KNOW THE END

22 RESULT IS TO ASK AGAIN FOR AUTHORITY TO COMMIT MONEY,

23 AND I HOPE WE CAN DO THAT.

24 NOW, AS YOU RECALL AT OUR LAST MEETING, I WAS

25 CHARGED AS PRESIDENT BY THE ICOC TO DEVELOP A STRATEGIC

1 PLAN WITH THE STAFF OF CIRM. AND CLAIRE POMEROY, AS I  
2 SAID BEFORE, SUGGESTED THAT IT WOULD BE WISE FOR ME TO  
3 BRING TO THIS GROUP A PLAN FOR A PLAN. AND IT TURNS  
4 OUT THAT DOING THIS BUYS THE CIRM, WITH THE COOPERATION  
5 OF THE ICOC, TURNS OUT TO BE A GRADUATE EXERCISE IN  
6 BAGLEY-KEENE GYMNASTICS. AND SO I HAVE RAISED OUR  
7 LEGAL FEES QUITE CONSIDERABLY BY CONFERRING WITH JAMES  
8 AND WITH SCOTT ON THESE ISSUES.

9 BUT ONE OF THE IMPORTANT POINTS IS THAT, AS I  
10 DESCRIBE THE PLAN TO YOU, IF IT IS TO BE A CIRM PLAN  
11 DEVELOPED BY US, I CAN TAKE NO FORMAL RECOMMENDATION OR  
12 APPROVAL OR A FORMAL SUGGESTION FROM YOU AS A BODY. I  
13 WILL EXPLAIN TO YOU HOW WE INTEND TO INVOLVE THE ICOC,  
14 BUT INSOFAR AS YOU DELEGATE ME TO DO SOMETHING OR YOU  
15 APPROVE ME TO DO SOMETHING, IT BECOMES AN ICOC PLAN AND  
16 THEN WE HAVE BAGLEY-KEENE THROUGHOUT THE WHOLE PROCESS.  
17 SO I BEG YOUR INDULGENCE THEN, AND LET ME WALK YOU  
18 THROUGH HOW WE PLAN TO DO IT.

19 FIRST OF ALL, LET ME SAY WHAT ARE THE  
20 PRINCIPLES -- LET ME JUST SAY WHAT THE CHALLENGE IS.  
21 WE HAVE A HUGE SCIENTIFIC PROJECT IN HAND HERE. A  
22 10-YEAR, \$3 BILLION PROJECT, IT IS A NEW AREA OF  
23 SCIENCE, TO PUT THIS TOGETHER IS A HUGE CHALLENGE. AND  
24 I WANT TO IMPRESS EVERYBODY WITH THAT. THIS IS NOT  
25 SOMETHING WE CAN SIT DOWN IN AN AFTERNOON AND FIGURE

1     OUT HOW TO DO, BUT THIS IS GOING TO BE A DETAILED, LONG  
2     PROCESS, AND WE'RE GOING TO HAVE TO PUT A LOT OF HARD  
3     WORK INTO MAKING JUDGMENTS ABOUT HOW TO PUT ALL THIS  
4     TOGETHER.

5             THE SECOND THING IS IT'S A LITTLE BIT  
6     DIFFERENT FROM PUTTING TOGETHER A STRATEGIC PLAN THAT  
7     ONE MIGHT DO IN A COMPANY OR ELSEWHERE IN THAT WE ARE A  
8     PUBLIC PROJECT, ONE IN WHICH THE PUBLIC IS HIGHLY  
9     INVESTED, WE ARE HIGHLY VISIBLE, AND WE HAVE A VERY  
10    COMPLEX CONSTITUENCY, WHICH IS VALUABLE TO US AND PART  
11    OF OUR -- PART OF WHAT WE DO, BUT IT ALSO MEANS THAT WE  
12    HAVE TO GO ABOUT THINGS IN A WAY THAT ACKNOWLEDGES AND  
13    ENGAGES THAT CONSTITUENCY.

14            SO HERE, IT SEEMS TO ME, ARE THE PRINCIPLES  
15    OF THE PLAN, THE PLAN AS I PROPOSE THEM.  FIRST OF ALL,  
16    SCIENCE IN THE SERVICE OF THERAPY.  WE WANT A PLAN  
17    THAT'S BASED IN WORLD-CLASS SCIENCE AND CLEARLY  
18    DIRECTED TOWARD THE DEVELOPMENT OF SPECIFIC THERAPIES  
19    IN THE CLINIC.  SECONDLY, WE WANT A WORKING PLAN.  WHAT  
20    I MEAN BY THAT IS ONE MIGHT CALL THIS NOT JUST A  
21    STRATEGIC PLAN, BUT WE WANT A STRATEGIC/OPERATIONAL  
22    PLAN.  IN ADDITION TO OVERALL GOALS AND OBJECTIVES, WE  
23    WANT A PLAN THAT WILL PROVIDE A SET OF DIRECTIONS FOR  
24    ACTION BY PROPOSING SPECIFIC TYPES OF GRANT PROGRAMS,  
25    SETTING PRIORITIES, DEVELOPING APPROXIMATE BUDGETS, AND

1 A COORDINATED TIME TABLE FOR SCIENTIFIC AND CLINICAL  
2 INITIATIVES.

3 FOR THE FIRST TWO YEARS, THE PLAN SHOULD GIVE  
4 A DETAILED PROGRAM OF ACTION WITH PROGRESSIVELY MORE  
5 FLEXIBLE PLANS FOR FUTURE YEARS, BUT IT SHOULD EXTEND  
6 OUT OVER THE ENTIRE PERIOD IN WHICH WE EXPECT TO BE  
7 FUNDED VIA PROPOSITION 71.

8 THIRD IS EXPERT AND STAKEHOLDER  
9 PARTICIPATION. THE PLAN WILL BE DEVELOPED IN  
10 CONSULTATION WITH EXPERTS AND STAKEHOLDERS, INCLUDING  
11 BASIC AND CLINICAL SCIENTISTS, PATIENT ADVOCATES,  
12 REPRESENTATIVES FROM NONPROFIT RESEARCH INSTITUTIONS,  
13 PHILANTHROPIC INSTITUTIONS, THE PRIVATE SECTOR, AND  
14 GOVERNMENT.

15 TRANSPARENCY, THE DEVELOPMENT OF THE PLAN  
16 WILL BE CARRIED OUT IN A TRANSPARENT WAY. WE WILL HAVE  
17 ONE OR MORE LARGE-SCALE PUBLIC MEETINGS, AND I'LL SAY  
18 MORE ABOUT THAT LATER. AND PARTICIPANTS, THE LIST OF  
19 PARTICIPANTS, AND THE ACCOUNTS OF ALL OUR MEETINGS WILL  
20 BE MADE AVAILABLE.

21 FURTHERMORE, WE PLAN TO SET UP A WEBSITE SO  
22 THAT PROGRESS IN DEVELOPMENT OF THE PLAN CAN BE  
23 FOLLOWED BY NOT ONLY ICOC MEMBERS AND OUR INTERESTED  
24 CONSTITUENTS IN ACADEMIC INSTITUTIONS, BUT ALSO BY THE  
25 LAY PUBLIC. THE PLAN MUST ENSURE FISCAL RESPONSIBILITY

1 AND ACCOUNTABILITY. WE NEED TO HAVE PRUDENT AND  
2 RESPONSIBLE USE OF FUNDS, AND WE NEED TO HAVE A  
3 MILESTONE.

4 AND FINALLY, TO BORROW A PHRASE FROM SHERRY  
5 LANSING, THIS SHOULD BE A LIVING PLAN. IT SHOULD HAVE  
6 A BUILT-IN EXPECTATION THAT AT PERIODIC INTERVALS IT  
7 WILL BE REVIEWED, PROGRESS EVALUATED, AND STRATEGIES  
8 UPDATED IN RESPONSE TO NEW SCIENTIFIC OPPORTUNITIES OR  
9 CHALLENGES.

10 I REALIZE I'M READING FROM A PREVIOUS  
11 VERSION, SO IF YOU WILL EXCUSE ME FOR ONE MOMENT.  
12 OKAY. WHAT ARE THE PHASES OF PLAN DEVELOPMENT? FIRST  
13 OF ALL, PREPARATION. WE WILL NEED TO DEFINE A  
14 SCIENTIFIC MISSION AND OVERALL GOALS. AND I WOULD  
15 ACTUALLY LIKE TO ASK THE ICOC TO DO THAT AT A FUTURE  
16 MEETING. WE WILL DEVELOP A PROJECT WORK PLAN, COMPLETE  
17 ORGANIZATIONAL STRUCTURE, IDENTIFY THE STAKEHOLDERS,  
18 AND SET UP OUR WEBSITE.

19 SECONDLY ARE DATA GATHERING AND ASSESSMENT.  
20 WE WILL START WITH THE SCIENTIFIC MEETING WE HELD LAST  
21 OCTOBER AND MINE THAT FOR IDEAS AND SUGGESTIONS. WE  
22 WILL THEN CONDUCT INTERNAL AND EXTERNAL INTERVIEWS,  
23 INCLUDING ICOC MEMBERS AS APPROPRIATE, AND THERE ARE  
24 SOME LIMITATIONS ON THAT AS I WILL DESCRIBE LATER, BUT  
25 CERTAIN ICOC MEMBERS HAVE PARTICULAR EXPERTISE, EITHER

1 SCIENTIFIC OR AS IN TERMS OF THEIR EXPERIENCE WITH  
2 GRANT-GIVING ORGANIZATIONS AND PATIENT ADVOCACY  
3 ORGANIZATIONS, AND WE WANT TO USE THAT EXPERIENCE.

4 THE THIRD, THEN, IS -- WE MAY HAVE FOCUS  
5 GROUPS. WE WOULD LIKE TO DO THAT AROUND SPECIFIC  
6 TOPICS, AND THEN WE WILL HAVE PERIODIC INFORMATION  
7 SUMMARIES FROM THE INTERVIEW. WE ALSO WILL HOLD A  
8 LARGE MEETING INVOLVING ICOC MEMBERS.

9 ANALYSIS, WE'LL ANALYZE ALL THESE REVIEWS,  
10 WE'LL IDENTIFY THEMES, DEFINE SHORT-TERM, MEDIUM-TERM,  
11 LONG-RANGE STRATEGIC OBJECTIVES, AND ORGANIZE ALL THIS  
12 IN A PRELIMINARY MANNER.

13 AND THEN FINALLY, WE WILL DEVELOP THIS INTO A  
14 REAL PLAN WITH PROPOSED DATES AND BUDGETS, DESCRIBING  
15 GRANT MECHANISMS TO BE USED. WE'LL DEVELOP A DETAILED  
16 TWO-YEAR PLAN FOR RFA'S, WE'LL PRESENT THIS DRAFT TO  
17 THE ICOC AND OTHER STAKEHOLDERS FOR COMMENT, AND THEN  
18 DEVELOP A FINAL DRAFT OF A STRATEGIC PLAN WHICH YOU MAY  
19 USE.

20 NOW, HOW WILL WE ENGAGE THE ICOC? AND IN  
21 ORDER TO DO THAT, WE NEED TO START WITH THE CONSTRAINTS  
22 OF BAGLEY-KEENE. I REALIZE THAT I DID THIS THIS  
23 MORNING. SO THE FIRST POINT IS THE ONE I'VE MADE, THAT  
24 IS, IF THE PLAN IS DEVELOPED BY THE CIRM, ICOC MEMBERS  
25 MAY MAKE SUGGESTIONS, BUT THE ICOC MAY NOT FORMALLY



1 APPROVE OR DIRECT HOW THE PLAN IS DEVELOPED.

2 SECONDLY, INDIVIDUAL MEMBERS MAY BE ON THE  
3 COMMITTEES OR BE INTERVIEWED, BUT THE TOTAL NUMBER WHO  
4 ARE FORMALLY INVOLVED MUST BE WELL BELOW A QUORUM.

5 THIRD, APPROVAL AND FORMAL MOTIONS OF THE  
6 ICOC WITH RESPECT TO THE PLAN ARE NOT APPROPRIATE UNTIL  
7 PRESENTATION OF THE FINAL DRAFT PLAN, AT WHICH POINT  
8 YOU HAVE A CHANCE TO APPROVE IT, MODIFY IT, SEND IT  
9 BACK, DIRECT US TO START ALL OVER AGAIN, OR WHATEVER  
10 YOU WISH TO DO, BUT UNTIL THAT TIME, WE WELCOME YOUR  
11 SUGGESTIONS, BUT NOT YOUR FORMAL ACTION OR DIRECTION ON  
12 ANY POINT.

13 HOW WILL THEN -- WITH ALL THIS, HOW WILL ICOC  
14 MEMBERS BE INVOLVED? FIRST OF ALL, WE WILL HAVE, I  
15 HOPE, SEVERAL MEMBERS ON AN ADVISORY COMMITTEE, AND  
16 I'LL DESCRIBE THAT IN JUST A MOMENT.

17 NOW, WE TALKED LAST TIME ABOUT WHETHER IT  
18 WOULD BE POSSIBLE TO INTERVIEW EACH ICOC MEMBER, WHICH  
19 IS WHAT WE ORIGINALLY STARTED WITH THE IDEA OF DOING,  
20 AND WE ARE TOLD THAT IS NOT POSSIBLE TO DO. EVEN IF WE  
21 HAVE A CONSULTANT WITH LOTS OF EMPLOYEES, SO THAT EACH  
22 ICOC MEMBER IS INTERVIEWED BY SOMEBODY SEPARATE, STILL  
23 ALL THIS INFORMATION FUNNELS BACK TOGETHER AND IS  
24 BROUGHT TOGETHER, AND AT THAT POINT WE VIOLATE  
25 BAGLEY-KEENE.

1                   HERE'S WHAT WE PROPOSE TO DO. WE PROPOSE TO  
2 HAVE A MEETING CALLED AND CONDUCTED BY CIRM TO WHICH WE  
3 INVITE ALL ICOC MEMBERS AND MEMBERS OF THE PUBLIC. IT  
4 WOULD BE A BAGLEY-KEENE NOTICED MEETING. THE AGENDA OF  
5 THE MEETING WOULD BE PERHAPS A COUPLE OF PRESENTATIONS.  
6 I WAS VERY STRUCK BY THE SUCCESS OF THIS IN THE  
7 INTELLECTUAL PROPERTY TASK FORCE, BRINGING IN PEOPLE  
8 WITH EXPERIENCE TO ACTUALLY TALK, SO IT'S A LEARNING  
9 EXPERIENCE FOR ALL OF US, AND THERE WOULD BE AMPLE TIME  
10 FOR DISCUSSION. WE WOULD RECORD ALL THIS, WE WOULD  
11 TAKE EVERYBODY'S IDEAS; HOWEVER, NO FORMAL MOTIONS OR  
12 RECOMMENDATION OR APPROVAL. IT WOULD BE OUR WAY OF  
13 GATHERING INFORMATION FROM YOU AND OF HEARING YOUR  
14 THOUGHTS IN A STRUCTURED CONTEXT ABOUT WHAT IT IS WE  
15 OUGHT TO BE DOING.

16                   THE SECOND, THEN, WOULD BE, AS I SAID,  
17 SEVERAL MEMBERS HAVE SPECIALIZED INTERESTS IN THIS AREA  
18 THAT WE WANT TO TAP INTO, BOTH AS REGARDS TO IDEAS  
19 ABOUT HOW TO DO STRATEGIC PLANS AND HOW TO DO GRANTS  
20 MAKING IN PARTICULAR, AND ALSO IN SOME CASES  
21 SCIENTIFIC. AND SO WE WILL INVOLVE SEVERAL MEMBERS IN  
22 THAT WAY. WE WILL GIVE YOU AN UPDATE ON PROGRESS. I  
23 SAID EACH MONTH. I REALLY MEAN AT EACH ICOC MEETING.  
24 I WOULD PRESENT AN UPDATE ON WHERE WE ARE WITH THE PLAN  
25 AND, AGAIN, RECEIVE YOUR COMMENTS. AND FINALLY, WE

1 WOULD PRESENT THE DRAFT PLAN FOR COMMENTS, AND THEN  
2 ADOPTION OF THE FINAL PLAN WITH MODIFICATIONS, AS  
3 NECESSARY.

4 NOW, HOW WOULD THE COMMITTEE STRUCTURE WORK?  
5 HOW WOULD THE ORGANIZATION WORK? WE WOULD START  
6 WORKING FROM THE TOP DOWN WITH AN ADVISORY COMMITTEE  
7 WHICH WOULD BE ADVISORY TO ME. I WOULD CHAIR THE  
8 COMMITTEE. IT WOULD HAVE ON IT, AND ALL OF THIS, BY  
9 THE WAY, THIS IS LISTED IN YOUR ITEM NO. 14 ON PAGE 5.  
10 THE CHAIR AND VICE CHAIR OF THE ICOC WOULD BE MEMBERS  
11 OF THAT COMMITTEE. WE WOULD HAVE ONE OR MORE OF THE  
12 FOLLOWING: PATIENT ADVOCATE, REPRESENTATIVE FROM THE  
13 PRIVATE SECTOR, SENIOR SCIENTIST, AND A CLINICIAN. AND  
14 THIS, AGAIN, WOULD NOT HAVE DECISION-MAKING AUTHORITY,  
15 BUT WOULD BE ADVISORY TO ME AND WOULD MEET EVERY MONTH  
16 OR SIX WEEKS, SORT OF IN THE INTERSTICES BETWEEN THE  
17 ICOC MEETINGS IN ORDER TO GET SORT OF HIGH LEVEL  
18 GUIDANCE.

19 THERE WILL BE A COORDINATING COMMITTEE WHICH  
20 WILL MEET WEEKLY RESPONSIBLE FOR OVERSEEING EACH WEEK'S  
21 PROGRESS, THE STRATEGY, ASSIGNMENTS, MONITOR THE SCOPE  
22 AND PROGRESS WITH CHANGES, AS NECESSARY, AND THIS WOULD  
23 BE CIRM SCIENTIFIC STAFF, AND WE WOULD HAVE IN SUPPORT  
24 A CONSULTANT. AND AS I'LL TELL YOU IN A MOMENT, WE  
25 HAVE BEEN IN DISCUSSION WITH A CONSULTANT WHO HAS

1 PROMISED US THEIR SENIOR PARTNER IN CHARGE OF GLOBAL  
2 LIFE SCIENCES FOR ONE TO ONE AND A HALF DAYS A WEEK WHO  
3 WOULD MEET WITH US ALONG WITH OTHER STAFF MEMBERS.

4 FINALLY, WE'D HAVE A DAILY WORKING GROUP THAT  
5 WOULD CONSIST OF CIRM STAFF AND CONSULTANTS WHO WOULD  
6 WORK WITH US ON THIS.

7 A FINAL ITEM IN THIS PART OF IT AS PART OF  
8 THE PLAN, WHAT IS THE ROLE OF THE PUBLIC? WE WILL HAVE  
9 PUBLIC COMMENT AT ICOC MEETINGS WHEN THE UPDATE IS  
10 GIVEN. THE SPECIAL ICOC MEETING WILL BE OPEN TO THE  
11 PUBLIC. THEY WILL BE ABLE TO PARTICIPATE IN THAT  
12 MEETING, AND THEN WE WILL HAVE A WEBSITE TO VIEW  
13 PROGRESS AND A MECHANISM FOR HAVING COMMENTS FROM THE  
14 PUBLIC COME IN TO THAT WEBSITE SO THAT WE CAN ACT ON  
15 IT.

16 NOW, LET ME ADDRESS THE ISSUE OF THE TIME  
17 SCALE. WHY ARE WE INTERESTED IN DOING THIS NOW? AND  
18 WHY IS IT IMPORTANT NOW? IN ORDER TO UNDERSTAND THAT,  
19 WE NEED TO WORK BACKWARDS. WE NEED TO SAY IF WE EXPECT  
20 OUR BOND MONEY IN THE SPRING OF 2007, AND IF WE WANT TO  
21 GET A FAST, LARGE-SCALE START AT THAT TIME, THEN WHAT  
22 WE WILL NEED TO DO IS TO ISSUE RFA'S IN THE FALL OF  
23 2007. AND WE NEED TO ISSUE NOT ONE OR TWO, BUT WE  
24 PROBABLY WILL NEED TO ISSUE A NUMBER OF THEM, AND SOME  
25 OF THESE MAY BE HIGH BUDGET ITEMS.

1                   CHAIRMAN KLEIN: DR. HALL, I THINK YOU MEANT  
2 TO SAY THE FALL OF 2006.

3                   DR. HALL: FALL OF 2006. RIGHT. THANK YOU.  
4 THAT MEANS IF WE'RE GOING TO MAKING COMMITMENTS,  
5 LARGE-SCALE COMMITMENTS, WE NEED TO DO THIS WITHIN A  
6 CONTEXT OF A THOUGHTFUL, ORDERED PLAN FOR ACTION, AND  
7 SO WE NEED OUR STRATEGIC PLAN DONE, I THINK, BY THE  
8 LATE SUMMER 2006. AND IF YOU BACK IT UP, THAT MEANS WE  
9 OUGHT TO GET STARTED SOON.

10                  SO WE HAVE THOUGHT ABOUT HOW WE MIGHT GO  
11 ABOUT THIS, AND WE HAVE DISCUSSED WITH THE GOVERNANCE  
12 SUBCOMMITTEE MEMBERS AND OTHERS WHETHER OR NOT WE  
13 SHOULD ENGAGE A CONSULTANT. AND OUR REASONS FOR  
14 NEEDING HELP ON THIS ARE THAT WE HAVE A LARGE WORKLOAD.  
15 WE EXPECT TO INTERVIEW UP TO 75 PEOPLE. THE LOGISTICS  
16 AND ORGANIZATION OF THIS WILL BE FORMIDABLE. WE THINK  
17 A CONSULTANT COULD BRING TOOLS AND EXPERIENCE, AND OUR  
18 CIRM PERSONNEL IS QUITE LIMITED.

19                  SO WE HAVE CONSIDERED THREE POSSIBILITIES.  
20 WE'VE INTERVIEWED TWO FIRMS. WE'VE ALSO CONSIDERED  
21 HIRING AND TRAINING PERSONNEL OURSELVES; THAT IS, WE  
22 COULD HIRE THREE PEOPLE TO HELP US WITH THIS PROJECT.  
23 THE PROBLEM WITH THAT IS SEVERALFOLD. ONE IS WE HIRE  
24 THEM AND THEN WE HAVE TO PAY THEM FOR THE WHOLE YEAR;  
25 THAT IS, WE DON'T HIRE THEM ON A TEMPORARY BASIS. WE

1     WOULD HAVE TO TRAIN THEM.  AND I THINK THAT ONE  
2     DISADVANTAGE OF THAT IS WE DON'T HAVE THE SENIOR LEVEL  
3     HELP THAT WOULD BE USEFUL IN PUTTING TOGETHER A PLAN  
4     LIKE THIS.  WE WOULD LIKE A FIRM THAT HAS HAD OR A  
5     GROUP OF PEOPLE WHO HAS HAD EXPERIENCE IN DOING THIS,  
6     THAT KNOWS WHAT'S HAPPENED IN OTHER CONTEXT, THAT HAS  
7     THE TOOLS AND THE EXPERTISE TO HELP US WITH THE  
8     LOGISTICS.

9                 SO WE INTERVIEWED TWO FIRMS, AND WE HAVE BEEN  
10    IN SERIOUS DISCUSSION WITH PRICE WATERHOUSE COOPERS.  
11    WHAT WE LIKE ABOUT THE TEAM THAT THEY BROUGHT IS THEY  
12    HAVE EXPERIENCE WITH PUBLIC INSTITUTIONS, THEY ARE  
13    EXPERIENCED IN WORKING WITH COMPLEX CONSTITUENCIES,  
14    THEY HAVE GOOD TOOLS, WE THINK, FOR LOGISTICS AND  
15    ANALYSIS.  THE LEAD ON IT WOULD BE A PARTNER WHO'S THE  
16    HEAD OF THEIR GLOBAL LIFE SCIENCES PROGRAM, AND WE'VE  
17    BEEN VERY IMPRESSED IN OUR DISCUSSIONS WITH THEIR  
18    ENTHUSIASM AND COMMITMENT FOR THE TASK.

19                SO WE HAVE DISCUSSED WITH THEM THE FOLLOWING  
20    PARAMETERS; THAT IS, THAT THE ENTIRE PROCESS, INCLUDING  
21    THE MEETING COST, THEIR PROFESSIONAL EXPENSES AND  
22    EXPENSES FOR -- AND THEIR EXPENSE FEES SHOULD ALL COME  
23    IN UNDER \$500,000.  THAT'S OUR TOP.  AND WE HAVE  
24    DISCUSSED WITH THEM A PARTIALLY DEFERRED PAYMENT  
25    SCHEDULE IN WHICH WE WOULD PAY THEM 20 PERCENT AT THE

1     END OF THE PROJECT WITH THE REST TO BE DEFERRED AT A  
2     LATER TIME.  AND WE WILL ATTEMPT TO RAISE THE MONEY FOR  
3     THIS FROM GIFTS.  NO PAYMENT IS NECESSARY UNTIL THE  
4     FALL.  AND IF THAT IS ULTIMATELY UNSUCCESSFUL, WE WOULD  
5     HAVE TO USE PUBLIC FUNDS.

6             MY OWN VIEW IS THAT WE WILL BE SUCCESSFUL IN  
7     THIS.  AND, FURTHERMORE, I THINK IF WE WERE TO WAIT  
8     UNTIL WE HAD PUBLIC FUNDS, ONE OF THE FIRST THINGS WE  
9     WOULD DO IS ENGAGE IN THIS PROCESS.  AND I WOULD SIMPLY  
10    SAY THAT ALTHOUGH \$500,000 SOUNDS LIKE A LOT OF MONEY,  
11    IF YOU THINK OF IT IN TERMS OF A \$3 BILLION PROJECT  
12    OVER TEN YEARS IN WHICH THIS IS A MAJOR, MAJOR EFFORT,  
13    IT REPRESENTS REALLY A MIDSIZE GRANT WITH ONE GRANT  
14    WITH DIRECT AND INDIRECT COSTS.  AND MY OWN VIEW IS  
15    THAT THIS IS WELL WORTH THE EXPENDITURE FOR THIS GROUP,  
16    AND IF WE CAN GET A GIFT THAT WILL FUND IT AND GET US  
17    STARTED, I WOULD LIKE TO START AS SOON AS POSSIBLE.

18            SO I ASK YOUR DISCUSSION.  NOW, I'M NOT  
19    ASKING YOUR COMMENT ON INDIVIDUAL SUGGESTIONS.  
20    THOUGHTS ON THE PLAN, THAT'S FINE; BUT NO ACTION, NO  
21    RECOMMENDATION; HOWEVER, I DO ASK YOU TO AUTHORIZE  
22    SPENDING THE MONEY FOR THIS IF WE CAN IDENTIFY FUNDS  
23    FOR IT.

24            DR. FRIEDMAN:  JUST A COUPLE OF THOUGHTS,  
25    ZACH.  ONE IS I THINK WE WOULD BE IRRESPONSIBLE IF WE

1 DIDN'T PUT AT LEAST THIS MUCH, IF NOT MORE, EFFORT AND  
2 COST. IF YOU SIMPLY TAKE \$500,000 AND DIVIDE IT BY \$3  
3 BILLION, IT'S A LUDICROUSLY SMALL AMOUNT OF MONEY. IF  
4 WE'RE GOING TO SPEND THE MONEY RESPONSIBLY, IF WE'RE  
5 GOING TO BE GOOD STEWARDS OF THE FULL AMOUNT OF MONEY,  
6 THIS IS -- I WOULDN'T SPEND A MOMENT DISCUSSING THIS  
7 AMOUNT. MY QUESTION WOULD BE IS THIS ENOUGH. I'M NOT  
8 TRYING TO SPEND MORE MONEY. MY POINT IS LET'S NOT  
9 FOCUS ON THE MONEY. LET'S FOCUS ON THE QUALITY OF THE  
10 PRODUCT THAT YOU ARE PUTTING TOGETHER.

11 AND SO I KNOW YOU'VE BEEN THINKING SERIOUSLY  
12 ABOUT THIS, AND I HAVE A COUPLE OF THOUGHTS I JUST  
13 WOULD LIKE TO SHARE THAT YOU PROBABLY ALREADY  
14 CONSIDERED. ONE IS THAT NOT JUST A SCIENTIFIC PLAN FOR  
15 HOW THIS GOES FORWARD, BUT ACTUALLY TIED VERY CLOSELY  
16 TO OUT-YEAR BUDGETS. BUDGETS SO THAT WE UNDERSTAND  
17 WHAT IT'S GOING TO COST TO DO CERTAIN KINDS OF  
18 ACTIVITIES. WE BUILD IN OUT-YEAR COSTS, AND EVEN MORE  
19 CRITICALLY WE BUILD IN THE UNEXPECTED, WHICH IS WE KNOW  
20 THERE'S GOING TO BE SOMETHING HAPPENING SEVEN YEARS  
21 FROM NOW THAT WE CAN'T ANTICIPATE, AND WE WILL REALLY  
22 BE SAD IF WE CAN'T FLEXIBLY MOVE MONEY TOWARD A HOTTER,  
23 PROMISING AREA. AND THERE ARE PEOPLE WHO MODEL THESE  
24 SORTS OF THINGS. I'M SURE YOU THOUGHT ABOUT THAT.

25 THE SECOND IS TO HAVE REALLY, AS MUCH AS WE



1 CAN, HAVE CLEAR, OBJECTIVE METRICS AND DELIVERABLES AT  
2 EACH POINT IN TIME SO THAT NOT ONLY WILL WE ABLE TO  
3 JUDGE HOW WE'RE DOING, BUT MORE IMPORTANTLY THE  
4 LEGISLATURE AND THE PUBLIC WILL SAY, WELL, THEIR  
5 STRATEGIC PLAN CALLED FOR X AND THEY SEEMED TO HAVE  
6 DELIVERED X OR THEY HAVEN'T, BUT THEN THEY DELIVERED Y  
7 AND THAT WAS GOOD.

8 AND THE LAST POINT I WOULD MAKE IS SINCE  
9 YOU'VE NOW BECOME A SORT OF MINI UNITED NATIONS DEALING  
10 WITH OTHER FOREIGN GOVERNMENTS, I WONDER WHETHER  
11 SINGAPORE OR THE UNITED KINGDOM OR SOMEBODY ELSE HAS A  
12 STRATEGIC PLAN THAT THEY'VE ARTICULATED. AND WHEN YOU  
13 INVITE PEOPLE TO COME AND PARTICIPATE IN THIS MEETING,  
14 YOU MIGHT WELL WANT TO INVITE SOME OF THEM TO SHARE  
15 THEIR IDEAS WITH US.

16 DR. HALL: INTERESTING YOU SHOULD SAY THAT.  
17 WE JUST HEARD A VERY INTERESTING PRESENTATION FROM THE  
18 PRESIDENT OF THE CANADIAN STEM CELL NETWORK THE OTHER  
19 DAY. AND ARLENE AND I LOOKED AT EACH OTHER AND SAID  
20 THE ICOC OUGHT TO HEAR THIS GUY.

21 DR. FRIEDMAN: I THINK THERE ARE PEOPLE WHO  
22 ARE WRESTLING WITH THE SAME PROBLEMS THAT WE ARE. I  
23 THINK IT'S AN EXCELLENT IDEA, AND I'M FULLY SUPPORTIVE.

24 DR. HALL: ANY OTHER SUGGESTIONS?

25 DR. PIZZO: FIRST OF ALL, I WANT TO CONCUR

1 WITH YOU, ZACH, THAT I THINK THE STRATEGIC PLANNING  
2 PROCESS IS CRITICALLY IMPORTANT. I THINK THAT IT  
3 SHOULD GO THROUGH THE CIRM GROUP AS YOU HAVE  
4 DELINEATED. I THINK THAT'S THE RIGHT PLACE FOR IT TO  
5 BE LOCATED. IT'S SIMILAR TO THE WAY WE DO STRATEGIC  
6 PLANNING AT OUR INSTITUTIONS WHERE WE HAVE BOARDS THAT  
7 OVERSEE OUR INSTITUTIONS, BUT THE WORK TAKES PLACE BY  
8 THE GROUP WHO ARE RESPONSIBLE FOR IT.

9 I THINK THE PROCESS THAT YOU'VE LAID OUT  
10 MAKES A LOT OF SENSE TO ME. THERE'S NO DOUBT THAT  
11 THERE NEEDS TO BE INVESTMENT AND RESOURCES. I WILL  
12 ONLY OFFER ONE FINAL PERSONAL CAVEAT, WHICH IS THAT I  
13 FEEL THAT IT'S BEST WHEN THE OWNERSHIP OF THE PROCESS  
14 IS REALLY THROUGH THE INDIVIDUALS WHO ARE LEADING IT,  
15 MEANING IN THIS CASE THE CIRM. I HAVE AN INNATE, SO  
16 THIS IS A PERSONAL CAVEAT, DISTRUST OF ENGAGING  
17 CONSULTANT GROUPS IN DOING IT BECAUSE I THINK IT  
18 DISTRACTS THE EFFORT, BUT THAT'S A PERSONAL CHOICE AND  
19 NOT TO EITHER DENY OR ALTER THE PLAN, BUT JUST TO OFFER  
20 THAT AS A PERSONAL VIEWPOINT.

21 AT THE END OF THE DAY, IF THERE IS A  
22 CONSULTANT GROUP ENGAGED, THE OWNERSHIP OF THIS HAS TO  
23 REMAIN WITH YOU AS CHAIR OR PRESIDENT, DEPENDING HOW  
24 YOU LOOK AT IT, AND THE ACCOUNTABILITY HAS TO LIE THERE  
25 AS WELL. MY CONCERN ABOUT CONSULTANT GROUPS IS THEY

1 COME IN AND GO AND THE OWNERSHIP IS NEVER QUITE VESTED  
2 WHERE IT BELONGS.

3 DR. HALL: YES. LET ME MAKE TWO POINTS. ONE  
4 THAT I FORGOT TO MAKE AND THE SECOND ONE WILL JUST  
5 ADDRESS THE POINT YOU JUST MADE OR CONTINUE THAT  
6 DISCUSSION.

7 NOTICE THAT I FELT THAT THE ICOC AS A WHOLE  
8 SHOULD MEET AND TALK ABOUT THIS. AND I WANTED TO SAY  
9 WE HAD SOME TALK LAST TIME ABOUT WHETHER OR NOT THERE  
10 SHOULD BE A SUBCOMMITTEE. I THINK THIS IS SO VITAL TO  
11 WHAT WE'RE DOING, THAT EVERY MEMBER OF THE ICOC OUGHT  
12 TO BE INVOLVED AND OUGHT TO BE PART OF THAT MEETING.  
13 SO I JUST WANT TO SAY THAT. I MEANT TO SAY THAT DURING  
14 THE PRESENTATION.

15 AND I COULDN'T AGREE WITH YOU MORE ABOUT THE  
16 SENSE OF OWNERSHIP. AND ONE OF THE THINGS WE MADE  
17 CLEAR TO BOTH FIRMS WAS THAT WE WERE NOT HIRING THEM TO  
18 DO A STRATEGIC PLAN FOR US. WE WERE HIRING THEM TO  
19 HELP US DO OUR STRATEGIC PLAN. AND WE'VE BEEN VERY,  
20 VERY CLEAR ABOUT THAT.

21 MR. SERRANO-SEWELL: THIS IS A  
22 WELL-THOUGHT-OUT DOCUMENT. THANK YOU. I JUST HAVE A  
23 COUPLE OF QUESTIONS.

24 DR. HALL: I'LL TAKE THAT COMMENT UNDER  
25 ADVISEMENT.

1                   MR. SERRANO-SEWELL: THE FIRST QUESTION IS  
2 THIS IS PROBABLY BETTER FOR JAMES. WHAT IS QUORUM?  
3 IT'S A NUMBER, QUORUM FOR THE ICOC, ASSUMING WE HAVE A  
4 FULL COMPLEMENT OF 29 MEMBERS.

5                   MR. HARRISON: NINETEEN.

6                   MR. SERRANO-SEWELL: NINETEEN. SO I SORT OF  
7 ON PAGE 4, POINT NO. 3, UNDER CONSTRAINTS OF  
8 BAGLEY-KEENE WHERE YOU SAY AT THE END OF THE PROCESS,  
9 THE TOTAL NUMBER OF ICOC MEMBERS ON THE COMMITTEE, I  
10 ASSUME YOU MEAN THE ADVISORY COMMITTEE?

11                  DR. HALL: YES.

12                  MR. SERRANO-SEWELL: AND THOSE INTERVIEWED, I  
13 ASSUME THAT'S THOSE NON-ICOC MEMBERS NOT ON THE  
14 ADVISORY COMMITTEE?

15                  DR. HALL: YES. WHO WOULD BE INTERVIEWED  
16 SEPARATELY FOR THEIR SPECIFIC EXPERTISE.

17                  MR. SERRANO-SEWELL: I'M OF THE OPINION THAT  
18 IT DOESN'T HAVE TO BE WELL BELOW QUORUM. IT HAS TO BE  
19 BELOW QUORUM CERTAINLY. I TOTALLY AGREE, BUT IT  
20 DOESN'T HAVE TO BE WELL BELOW QUORUM. I DON'T KNOW  
21 WHAT WELL BELOW QUORUM IS. IS IT TEN? IS IT EIGHT OR  
22 16? SO THAT'S SOMETHING TO CONSIDER BECAUSE I AGREE  
23 WITH YOU. I WANT TO INVOLVE AS MANY ICOC MEMBERS AS  
24 POSSIBLE. I DON'T WANT TO PUT ANY FALSE SORT OF  
25 CONSTRAINTS ON THAT.

1 DR. HALL: I APPRECIATE THAT COMMENT, DAVID.  
2 WE WANT TO INVOLVE AS MANY AS POSSIBLE. WHAT WE DON'T  
3 WANT TO DO IS INADVERTENTLY STEP OVER THE LINE, AND  
4 THAT'S WHERE WE'RE JUST GOING TO HAVE TO BE VERY  
5 CAREFUL ABOUT THAT.

6 MR. SERRANO-SEWELL: WELL, THE NUMBER IS 18,  
7 AND THAT'S THE LINE IN THE SAND; IS THAT RIGHT, JAMES?

8 MR. HARRISON: THAT IS CORRECT.

9 MR. SERRANO-SEWELL: SO YOU COULD TALK TO 17.  
10 UP TO SEVENTEEN ICOC MEMBERS COULD BE IN THE LOOP AND  
11 INVOLVED.

12 NOW, AS TO THE ADVISORY COMMITTEE ITSELF, WHO  
13 WILL APPOINT THE MEMBERS TO THIS ADVISORY COMMITTEE?

14 DR. HALL: I WILL.

15 MR. SERRANO-SEWELL: AND IS THIS COMMITTEE AN  
16 AD HOC COMMITTEE OF THE ICOC?

17 DR. HALL: NO. IT'S ADVISORY TO ME, AND IT  
18 IS -- IT WILL BE DONE BY BAGLEY-KEENE BECAUSE WE  
19 ANTICIPATE HAVING SEVERAL ICOC MEMBERS ON IT, BUT I  
20 WILL APPOINT THEM AND THEY'RE ADVISORY TO ME.

21 CHAIRMAN KLEIN: IT'S VERY IMPORTANT WHAT HE  
22 JUST SAID. UNDER DR. HALL'S PROPOSAL, THIS WOULD BE A  
23 BAGLEY-KEENE COMMITTEE.

24 DR. HALL: WELL, IT WOULD BE HELD UNDER  
25 BAGLEY-KEENE CONDITIONS.

1                   CHAIRMAN KLEIN:  THESE ARE PUBLIC MEETINGS.

2                   DR. HALL:  THESE ARE PUBLIC MEETINGS.

3           ANYTHING MADE AVAILABLE TO THE ADVISORY COMMITTEE  
4           MEMBERS WILL BE MADE AVAILABLE TO THE PUBLIC.  IN THAT  
5           SENSE IT WOULD BE A BAGLEY-KEENE MEETING.  BUT IT WOULD  
6           BE ADVISORY TO ME AND, AGAIN, WOULD NOT TAKE FORMAL  
7           ACTION.  AND THAT'S THE ONLY WAY WE CAN HAVE ICOC  
8           MEMBERS ON IT.

9                   MR. SERRANO-SEWELL:  I WOULD DISAGREE WITH  
10          THAT ASSERTION.  IT'S SORT OF CLEVER FOR THE ICOC TO  
11          EMPOWER ITS PRESIDENT TO CREATE -- TO AUTHORIZE ITS  
12          PRESIDENT TO CREATE AN ADVISORY COMMITTEE.

13                  DR. HALL:  NO, YOU HAVE NOT DONE THAT, AND  
14          YOU'RE NOT GOING TO DO IT.  YOU'RE NOT GOING TO  
15          AUTHORIZE ME UNDER THIS PLAN.  THAT'S THE WHOLE POINT.  
16          IF YOU TELL ME TO DO IT, THEN IT'S AN ICOC THING, BUT I  
17          DON'T ASK FOR YOUR DIRECTION OR PERMISSION TO DO IT.  
18          I'M PURELY GIVING YOU AN INFORMATIONAL DISCUSSION ABOUT  
19          WHAT I PLAN TO DO IN CARRYING OUT THE CHARGE THAT YOU  
20          GAVE ME, THE BROAD CHARGE THAT YOU GAVE ME.

21                  MR. SERRANO-SEWELL:  I HAVE ANOTHER QUESTION  
22          THEN.  JUST INDULGE ME.

23                  DR. HALL:  WE HAVE JEFF AND THEN WE HAVE --

24                  MR. SERRANO-SEWELL:  I WANT TO ASK THE  
25          COUNSEL A QUESTION.  WHEN DO WE HAVE AN AD HOC

1 COMMITTEE OF THE ICOC? WE AS AN ICOC HAVE TO TAKE  
2 ACTION TO SAY WE'RE CREATING A SUBCOMMITTEE. I KNOW  
3 WE'RE DANCING A FINE LINE HERE.

4 MR. HARRISON: WHEN THE ICOC TAKES FORMAL  
5 ACTION TO EITHER APPOINT AN ADVISORY COMMITTEE OR A  
6 DELEGATED BODY. AND IF IT'S AN ADVISORY BODY OF MORE  
7 THAN TWO MEMBERS, THEN IT IS SUBJECT TO BAGLEY-KEENE.  
8 IF IT'S A DELEGATED BODY OF ANY SIZE, THEN IT'S SUBJECT  
9 TO BAGLEY-KEENE.

10 MR. SERRANO-SEWELL: WHEN YOU HAVE SO MANY  
11 ICOC MEMBERS IN THE SAME ROOM, YOU HAVE A BAGLEY-KEENE  
12 ISSUE; IS THAT RIGHT?

13 MR. HARRISON: POTENTIALLY YES, DEPENDING ON  
14 THE CIRCUMSTANCES.

15 MR. SERRANO-SEWELL: WHAT'S THAT NUMBER?

16 MR. HARRISON: A QUORUM.

17 MR. SERRANO-SEWELL: IT WOULD DEPEND. IF  
18 IT'S A QUORUM --

19 MR. HARRISON: FOR EXAMPLE, THERE ARE OPEN  
20 PUBLIC MEETINGS TO DISCUSS ISSUES OF RELEVANCE TO THE  
21 AGENCY AS A WHOLE THAT ARE ATTENDED BY A MAJORITY OF  
22 MEMBERS. AS LONG AS THE BUSINESS OF THE AGENCY IS NOT  
23 DISCUSSED ARE NOT SUBJECT TO BAGLEY-KEENE. SO THERE  
24 ARE SOME EXCEPTIONS, BUT GENERALLY WHEN YOU HAVE A  
25 QUORUM OF MEMBERS EITHER IN A DISCUSSION IN THE SAME

1 PLACE AT THE SAME TIME OR SERIALLY, YOU HAVE A  
2 BAGLEY-KEENE ISSUE.

3 MR. SERRANO-SEWELL: MY FINAL QUESTION TO  
4 COUNSEL IS I SEE FOR THIS ADVISORY COMMITTEE AT A  
5 MINIMUM ONE, TWO, THREE, FOUR, FIVE, AT A MINIMUM SIX  
6 ICOC MEMBERS, POTENTIALLY MORE.

7 MR. HARRISON: THAT'S WHY IT WILL BE A  
8 BAGLEY-KEENE BODY. IT WILL MEET SUBJECT TO  
9 BAGLEY-KEENE.

10 MR. SERRANO-SEWELL: IT WOULD MEET SUBJECT TO  
11 BAGLEY-KEENE, BUT IT'S NOT AN AD HOC COMMITTEE.

12 MR. HARRISON: CORRECT. AN ADVISORY  
13 COMMITTEE TO THE PRESIDENT.

14 DR. HALL: LET ME SAY THAT AS A MATTER OF  
15 INFORMATION, THE PEOPLE ON THAT COMMITTEE WILL NOT  
16 NECESSARILY BE LIMITED TO ICOC.

17 MR. SERRANO-SEWELL: DOESN'T SAY THAT.  
18 SENIOR SCIENTISTS.

19 DR. HALL: THAT'S WHY I SAID IT BECAUSE IT'S  
20 NOT MADE CLEAR ON THERE, BUT THAT'S MY INTENTION.  
21 THERE WILL BE SOME ICOC MEMBERS, BUT THERE MAY VERY  
22 WELL BE PEOPLE ON IT WHO ARE NOT ICOC MEMBERS.

23 MR. SHEEHY: WELL, JUST IN TERMS OF THIS  
24 PROCESS, IT SEEMS TO ME THAT THERE SHOULD BE A PEER  
25 REVIEW OF THIS SCIENTIFIC PLAN, AND THAT THE LOGICAL



1 PLACE TO DO THE PEER REVIEW WOULD BE IN THE GRANTS  
2 WORKING GROUP SO WE CAN HAVE THE PLAN SCORED AND  
3 REVIEWED BY SCIENTISTS WITH AN OBJECTIVE VIEW.

4 ALSO, IT SEEMS THAT IT SHOULD GO THROUGH THE  
5 STANDARDS WORKING GROUP TO MAKE SURE THAT IT'S  
6 CONSISTENT WITH THE ETHICAL STANDARDS THAT WE'VE JUST  
7 ADOPTED.

8 DR. HALL: I APPRECIATE THOSE COMMENTS, AND I  
9 WILL TAKE THEM UNDER CONSIDERATION.

10 MR. SHEEHY: I DON'T THINK I CAN VOTE FOR  
11 THIS. I DON'T KNOW IF I CAN AUTHORIZE THE MONEY.

12 MR. SERRANO-SEWELL: YEAH. I WOULD BE  
13 UNCOMFORTABLE WITH AUTHORIZING THE MONEY UNTIL I HAVE  
14 SOME MORE CLARIFICATION ON THESE ISSUES; NAMELY, THE  
15 COMPOSITION OF THE ADVISORY COMMITTEE.

16 DR. HALL: I THINK THAT'S YOUR CHOICE.

17 MR. SERRANO-SEWELL: I KNOW IT'S MY CHOICE.

18 DR. HALL: IT'S YOUR CHOICE AS AN ICOC.

19 MR. SERRANO-SEWELL: IT IS.

20 DR. BRYANT: I'M TRYING TO VISUALIZE THE ROLE  
21 OF A CONSULTING FIRM AS OPPOSED TO A CONSULTANT WHO WE  
22 MIGHT HIRE JUST AS AN INDIVIDUAL RATHER THAN AS A  
23 COMPANY, WHICH WILL GET AROUND THE OWNERSHIP ISSUES. I  
24 IMAGINE THAT THIS PERSON IS MORE OF AN ORGANIZATIONAL  
25 AND COORDINATION CONSULTANT RATHER THAN A SUBSTANCE

1     GENERATOR.  SO THE SUBSTANCE OF THE PLAN WILL COME FROM  
2     OTHER SOURCES, SO THIS IS SOMEONE WHO WILL FACILITATE  
3     BASICALLY.

4             DR. HALL:  YES.  THAT IS TRUE, AND THEIR  
5     MAJOR CONTRIBUTION, IN MY MIND, WILL BE TO HELP US WITH  
6     ORGANIZATIONAL ISSUES AND SOME STRATEGIC ISSUES IN  
7     DOING THE PLAN.  AND PART OF THAT IS -- I DIDN'T,  
8     BECAUSE TIME SEEMED SHORT, I DIDN'T GO INTO IT, BUT THE  
9     FIRM HAS DONE A STRATEGIC PLAN, FOR EXAMPLE, FOR  
10    MULTIPLE MYELOMA RESEARCH FOUNDATION.  THEY'VE WORKED  
11    FOR A NUMBER OF DIFFERENT GROUPS.  THE ONE THAT WAS  
12    MOST INTERESTING TO ME IN THIS REGARD IS THAT THEY WORK  
13    FOR THE STATE OF ARIZONA IN SETTING UP SOMETHING  
14    CALLED, THAT YOU MAY KNOW OF, CALLED THE INSTITUTE OF  
15    TRANSLATIONAL GENOMICS, HEADED BY JEFF TRENT, WHO'S THE  
16    DIRECTOR THERE.  SO IN THAT THIS WAS DIRECTLY MANDATED  
17    BY THE LEGISLATURE AND THE GOVERNOR, AND SO THERE WAS A  
18    LOT OF POLITICAL SENSITIVITY.  AND THEY HELPED THEM SET  
19    THE WHOLE THING; AND THEN ONCE JEFF TRENT CAME ON  
20    BOARD, THEY HELPED HIM WITH THE STRATEGIC PLAN, AND HE  
21    SPOKE VERY, VERY HIGHLY OF THEM.

22            MR. SHESTACK:  IS THAT T-GEN?

23            DR. HALL:  THAT'S T-GEN.  YOU MAY KNOW OF  
24    HIM.  SO THAT SEEMED IN MANY WAYS A SORT OF COMPARABLE  
25    PROJECT, NOT EXACTLY, BUT INVOLVING THAT.  IN THE

1 DISCUSSIONS, I WAS VERY IMPRESSED WITH THEIR CONCERN  
2 THAT WE GET BUY-IN FROM ALL OF OUR CONSTITUENTS, AND  
3 THEY BRING TOOLS AND THEY BRING INTERVIEW TEMPLATES  
4 THAT ARE AT LEAST A START. THEY WILL CARRY OUT MANY OF  
5 THE INTERVIEWS, AND SO THEY ARE A VERY EXPERIENCED  
6 TEAM. THE CORE OF THEM HAVE WORKED TOGETHER ON OTHER  
7 PROJECTS. SO IT'S NOT JUST A MATTER OF HIRING SEVERAL  
8 INDIVIDUALS. IT REALLY IS BRINGING IN PEOPLE WHO HAVE  
9 DONE SOMETHING LIKE THIS BEFORE, AND WE VERY MUCH PUT  
10 OUR OWN STAMP ON IT. THERE'S NOT GOING TO BE ANY  
11 QUESTION ABOUT THAT AND HAVE ALREADY DONE SO IN  
12 DISCUSSIONS WITH THEM. I SAID, NO, WE'RE NOT GOING TO  
13 DO THIS, WE'RE GOING TO DO THIS.

14 DR. BRYANT: SO THE PLANS THAT THEY'VE  
15 DEVELOPED -- THAT HAVE BEEN DEVELOPED FOR THESE OTHER  
16 INSTITUTIONS AND THE STATE OF ARIZONA, HAVE THEY BEEN  
17 CONSIDERED SUCCESSFUL? ARE THEY BEING USED? I JUST --  
18 I HAVE NO EXPERIENCE IN THIS AREA.

19 DR. HALL: YES. I DON'T KNOW THAT. I MEAN I  
20 HAVE NOT LOOKED SPECIFICALLY AT THAT. FOR THE CONTENT  
21 OF THE PLAN, WHO'S GOING TO BE RESPONSIBLE FOR IT IS  
22 US. AND I THINK THAT WE'RE THE ONES THAT WILL HAVE TO  
23 WORK THROUGH THESE THEMES, GATHER ALL THE INFORMATION  
24 FROM ALL THE SOURCES, AND IT'S OUR JUDGMENT IN THE END  
25 THAT WE'LL TRY TO SORT ALL OF THESE THINGS OUT. AS THE

1     *NEW YORK TIMES* SAID, HOW WE PLACE OUR BETS IS REALLY  
2     GOING TO BE OURS.

3             ONE THING I DID LEARN IN TALKING TO PEOPLE IS  
4     ALMOST EVERYBODY SAYS, LOOK, THEY DON'T HAVE THE  
5     KNOWLEDGE BASE THAT YOU DON'T HAVE. THEY'RE NOT GOING  
6     TO COME IN AND TELL YOU YOU SHOULD DO THIS, THAT, AND  
7     THE OTHER. WHAT THEY ARE IS TO HELP YOU GET THE  
8     INFORMATION YOU NEED, ORGANIZE IT, AND THEN IMPOSE YOUR  
9     OWN VALUES ON IT. I THINK THAT'S, AT LEAST, HOW I SEE  
10    IT.

11            DR. PENHOET: IF I MIGHT, I'D JUST LIKE TO  
12    TAKE US BACK TWO OR THREE MEETINGS. WE DID HAVE AN  
13    EXTENSIVE DISCUSSION, LED BY DAVID BALTIMORE, WHO'S NOT  
14    HERE TODAY, ON THE ISSUE OF WHO IS RESPONSIBLE FOR  
15    DEVELOPING A STRATEGIC PLAN. WE CAME UP WITH A CLEAR  
16    DIRECTIVE, THAT IT SHOULD BE DEVELOPED BY MANAGEMENT  
17    AND REVIEWED BY THE BOARD. I BELIEVE WE ACTUALLY VOTED  
18    THAT AS THE PRINCIPLE UPON WHICH THIS HAS BEEN BASED.

19            I BELIEVE I'VE HEARD SOME RUMBLINGS AROUND  
20    THIS TABLE THAT, IN FACT, WE'RE REVISITING THE ISSUE OF  
21    WHO HAS THE RESPONSIBILITY. WE MADE A CLEAR  
22    DESIGNATION TO ZACH THAT, AS THE PRESIDENT, HE HAD THE  
23    RESPONSIBILITY FOR DEVELOPING A PLAN IN CONSULTATION,  
24    ETC., BUT ULTIMATELY IT WAS HIS RESPONSIBILITY TO  
25    PRODUCE A PLAN WHICH WOULD BE PRESENTED FOR APPROVAL OR

1 NOT TO THIS BOARD, BUT WE SPECIFICALLY SAID THAT THE  
2 BOARD ITSELF WAS NOT TAKING UNTO ITSELF THE TASK OF  
3 CREATING THE STRATEGIC PLAN.

4 SO I JUST WANTED TO REFRESH OUR MEMORIES, AND  
5 DAVID'S THOUGHTS ARE STILL RINGING IN MY EARS, THAT HE  
6 WAS NOT THE ONLY PERSON IN FAVOR OF THIS MODEL, BUT HE  
7 WAS CERTAINLY THE MOST -- I SHOULDN'T SAY ARTICULATE.  
8 EVERYBODY HERE. HE WAS THE MOST VOCIFEROUS AND  
9 REPRESENTED THAT VIEW. I JUST WANTED TO REMIND  
10 EVERYBODY THAT WE HAVE APPROACHED THIS ISSUE BEFORE.  
11 WE MADE A DECISION AS A BODY TO GO FORWARD IN THIS  
12 PARTICULAR WAY. AND I THINK THAT ZACH HAS TAKEN THAT  
13 TO HEART AND BROUGHT THIS PROPOSAL TO US TODAY IN  
14 RESPONSE TO US DELEGATING THAT AUTHORITY TO HIM.

15 MS. LANSING: I JUST WANT TO SECOND THAT. I  
16 THINK IT'S EXTREMELY IMPORTANT THAT AS A BOARD WE  
17 EXERCISE OUR OVERSIGHT RESPONSIBILITIES, BUT I ALSO  
18 THINK IT'S EXTREMELY IMPORTANT THAT WE LET THE PEOPLE  
19 WHO ARE RUNNING THE INSTITUTE RUN IT AND DO WHAT IS  
20 BEST FOR THE SCIENCE AND FOR THE WORK THAT WE'RE ALL  
21 TRYING TO DO. IF WE GET INTO A BOARD THAT MICROMANAGES  
22 EVERYTHING, WE WILL NOT MOVE FORWARD.

23 SO I WOULD LIKE TO CALL FOR THE VOTE, BUT I  
24 DON'T KNOW THAT WE HAVE A QUORUM.

25 MS. SAMUELSON: I'VE BEEN WAITING TO SPEAK,

1       SO I WANT TO HAVE AN OPPORTUNITY.

2                   MS. LANSING:   SURE.   I'M SORRY.

3                   MS. SAMUELSON:   I DON'T WANT TO INTERRUPT  
4   YOU.   THIS IS IMPORTANT.   I THINK TO FOLLOW ON ED'S  
5   POINT AND PIECES OF VARIOUS OTHER POINTS, I THINK THE  
6   DEVIL IS IN THE DETAILS.   ULTIMATELY AS I WAS SORT OF  
7   TRACING THAT OUT AND TRYING TO STAND BACK AND LEAVE THE  
8   RESPONSIBILITY ON DR. HALL'S SHOULDERS, ULTIMATELY I  
9   THINK WE ARE GOING TO HAVE TO OWN THIS PLAN BECAUSE  
10  WHAT WE'RE TRYING TO DO IS UNPRECEDENTED, AND IT'S  
11  EXCEEDINGLY DIFFICULT, AND THERE ARE GOING TO BE  
12  MOMENTS WHEN IT'S POLITICALLY UNPOPULAR WHEN THERE ARE  
13  FAILED CLINICAL TRIALS OR WE'RE NOT GETTING CURES AT  
14  FIVE YEARS, EIGHT YEARS, OR EVEN TEN YEARS.   WE'RE  
15  GOING TO HAVE TO DEFEND THAT AND FIGHT FOR WHATEVER THE  
16  BEST OUTCOME OF THE EXPENDITURE THAT \$3 BILLION IS.

17                   SO IT'S FAR FROM WHAT IT STARTED FEELING LIKE  
18  FOR A SECOND TO ME, THAT WE'RE TURNING OVER TO A  
19  CORPORATE CEO A PRODUCTION OF SOME PRODUCT LINE, AND WE  
20  CAN THEN JUST REVIEW WHETHER IT'S MEETING THE BOTTOM  
21  LINE AT THE END OF YEAR.   THAT'S FAR FROM, OF COURSE,  
22  THE INVOLVEMENT WE HAVE TO HAVE IN THIS.   WE HAVE TO  
23  HAVE A HUGE STAKE IN IT.   SO IT SEEMS TO ME ULTIMATELY  
24  IT'S GOT TO BE THE ICOC'S PLAN, CERTAINLY COMING FROM  
25  YOU AND WORKING IN PARTNERSHIP WITH YOU.   BUT I THINK

1 WE'VE GOT TO BE ENGAGED IN THE THING FROM -- IN A VERY  
2 INTEGRATED WAY.

3 THE OTHER THOUGHT THAT OCCURS TO ME IS WE  
4 HAVE THIS VERY UNDERUTILIZED BRAIN TRUST IN THE  
5 RESEARCH FUNDING WORKING GROUP NOW. AND OUR BUDGET IS  
6 PROVIDING FOR NOT ONE MEETING PRESENT IN CALIFORNIA OF  
7 THAT WORKING GROUP ALL YEAR. IT'S THREE CONFERENCE  
8 CALLS, I THINK, AND THERE'S A BRAIN TRUST THERE THAT WE  
9 PULLED TOGETHER THIS WORLD-CLASS BODY. WHY WOULD WE  
10 NOT SPEND MONEY ON THEM RATHER THAN ON -- GET THEIR  
11 EXPERTISE BECAUSE THEY'RE ALREADY IN THE FIELD? WHY  
12 NOT PUT THEM TO USE, AND WE HAVE A BAGLEY-KEENE  
13 EXCEPTION WHICH WAS, AS I UNDERSTAND IT, REALLY  
14 INTENDED TO GET THE BEST OUT OF THOSE MINDS. ALL OF  
15 THAT MAY BE AT A REVIEW POINT AFTER YOU'VE HAD THE  
16 OPPORTUNITY TO PUT A PLAN ON PAPER, BUT NOT IN A WAY  
17 THAT WE ARE REALLY FEELING THAT WE CAN ONLY SORT OF  
18 VOTE UP OR DOWN AND NOT REALLY GET INTO THE WEEDS OF IT  
19 BECAUSE IT SEEMS TO ME WE HAVE TO.

20 DR. PIZZO: JUST PERHAPS A COMMENT ON THAT,  
21 JOAN. I APPRECIATE YOUR COMMENTS. I HAVEN'T HEARD IT  
22 THE SAME WAY, SO LET ME JUST SAY THE WAY I'VE HEARD IT.  
23 I VIEW THIS AS AN ONGOING, ITERATIVE PROCESS. I WAS  
24 SPECIFIC ABOUT OWNERSHIP BECAUSE I THINK THAT IN THE  
25 DEVELOPMENT OF ANY STRATEGIC PLAN, JUST AS WE WOULD DO

1 IN OUR OWN INSTITUTIONS, THERE HAS TO BE A STARTING  
2 POINT. AND THAT'S WHERE I SEE OUR ROLE, AS BEING BOARD  
3 OF TRUSTEE OVERSIGHT OVER THE PROCESS. WE'LL BE  
4 INVOLVED IN THE PROCESS, BUT ULTIMATELY IT COMES BACK  
5 FOR PRESENTATION, REVIEW, AND ULTIMATE APPROVAL.

6 SO I THINK, TO ME, THIS IS A WAY OF ENGAGING  
7 THE ACCOUNTABILITY PARTICULARLY WITH REGARD TO THE  
8 SCIENTIFIC PLANNING IN THE GROUP THAT I THINK IS I'M  
9 GOING TO HELP STAGE THE DISCUSSION IN A WAY THAT WILL  
10 MAKE US OR ALLOW US TO DRAW THE APPROPRIATE CONCLUSIONS  
11 AND THEN APPROVE THOSE AS WE DEEM NECESSARY. I THINK  
12 THAT I DON'T HAVE THE SENSE THAT WE ARE IN ANY WAY  
13 MINIMIZING OUR RESPONSIBILITIES. I THINK WE HAVE  
14 TREMENDOUS RESPONSIBILITIES, EACH OF US, IN THE  
15 OVERSIGHT OVER THIS, BUT I THINK THIS IS AN APPROPRIATE  
16 COLLABORATION WITH THE CIRM THAT ALLOWS US TO MOVE THE  
17 AGENDA FORWARD.

18 DR. HALL: WELL, LET ME JUST SAY, IN RESPONSE  
19 TO BOTH OF THOSE THINGS, THAT I TOOK THE CHARGE THAT I  
20 WAS GIVEN LAST TIME VERY SERIOUSLY AND SPENT A LOT OF  
21 TIME EXPLORING, AS I SAY, RUNNING UP OUR LEGAL FEES  
22 TRYING TO FIGURE OUT WAYS IN WHICH THE ICOC COULD BE  
23 INVOLVED THAT WOULD STILL MAINTAIN THIS AS A CIRM  
24 FUNCTION AS I WAS DIRECTED TO DO. SO CERTAINLY IT'S  
25 NOT MY INTENT AT ALL TO -- I WANT VERY MUCH TO WORK



1 WITH THE ICOC; ON THE OTHER HAND, WE NEED TO DO IT IN A  
2 WAY THAT'S LEGAL AND IN A WAY THAT CARRIES OUT THE  
3 SENSE OF THE MOTION THAT WAS MADE LAST TIME AND THE  
4 CHARGE THAT WAS GIVEN TO ME LAST TIME.

5 DR. STEWARD: I JUST WANTED TO SAY THAT I  
6 THINK UNFORTUNATELY WE NOW LACK A QUORUM, AND IT ISN'T  
7 COMING BACK. SO I JUST WONDER IF -- ALL THE THINGS  
8 WE'RE TALKING ABOUT ARE IMPORTANT ISSUES, BUT I WONDER  
9 IF WE OUGHT TO PUT THEM OFF AND REALLY REDISCUSS THEM  
10 AT THE NEXT MEETING WHEN EVERYBODY IS HEAR TO LISTEN.

11 CHAIRMAN KLEIN: THERE'S BEEN A GREAT DEAL OF  
12 THOUGHT PUT INTO THIS BY DR. HALL, AND HE SHOULD BE  
13 COMMENDED FOR THIS EFFORT AND ORGANIZATION OF THIS  
14 PLAN. I THINK WE ARE SIGNIFICANTLY BELOW A QUORUM. WE  
15 SHOULD PRIORITIZE THIS, I THINK, FOR THE NEXT BOARD  
16 MEETING, BUT PLEASE WE'LL, WITH THE DIRECTION OF  
17 COUNSEL, CAREFULLY MAKE CERTAIN THAT WE'RE OPERATING  
18 WITH INPUT WITHIN THE PROPER LIMITATIONS. BUT THOSE OF  
19 YOU WHO HAVE DEVELOPED INDIVIDUAL IDEAS AND INPUT  
20 PLEASE TALK TO DR. HALL SO WE CAN RESOLVE THIS. AS DR.  
21 HALL SAID, WE NEED TO LAUNCH THIS IMMEDIATELY, AND WE  
22 NEED TO LAUNCH THIS WITH THE BENEFIT OF THE ADVICE OF  
23 THE MEMBERS OF THE BOARD WHO COME FROM DIVERSE  
24 EXPERIENCE.

25 I THINK THAT HE'S PUT OUTSTANDING EFFORT INTO

1 TRYING TO DEVELOP A MODEL HERE, AND WE SHOULD SEE  
2 BETWEEN NOW AND THE NEXT MEETING WHAT WE CAN DO TO MAKE  
3 CERTAIN WE CAN MOVE THIS FORWARD.

4 DR. STEWARD: JUST REAL QUICK. I REALLY WANT  
5 TO CONGRATULATE ZACH AND THE STAFF FOR REALLY THINKING  
6 VERY, VERY HARD ABOUT THIS. IT'S VERY OBVIOUS THAT YOU  
7 PUT A LOT OF THOUGHT INTO HOW TO DO THIS WITHIN  
8 BAGLEY-KEENE RESTRICTIONS. I JUST WANT TO CONGRATULATE  
9 YOU ON HARD WORK WELL DONE.

10 CHAIRMAN KLEIN: DR. FRIEDMAN, DR. POMEROY,  
11 AND DR. PIZZO.

12 DR. FRIEDMAN: IF COULD JUST TAKE BOB'S  
13 COMMENT ONE STEP FURTHER, THIS IS SUPREMELY IMPORTANT.  
14 WHAT I WOULD LIKE TO SUGGEST IS THE MINUTES REFLECT  
15 THAT THOSE PEOPLE WHO HAVE RESERVATIONS OR CONCERNS OR  
16 WANT TO SEE CERTAIN THINGS BUILT INTO THIS PROCESS  
17 E-MAIL OR COMMUNICATE WITH YOU DIRECTLY SO THAT THEIR  
18 ISSUES WILL BE AT LEAST BROUGHT TO YOUR ATTENTION PRIOR  
19 TO THE NEXT MEETING. WHAT THAT MEANS IS THAT AT THE  
20 NEXT MEETING, WE CAN REACH A DEFINITIVE CONCLUSION. I  
21 DON'T WANT PEOPLE THINKING ABOUT THIS AND NOT  
22 COMMUNICATING IT WITH YOU. IF WE COULD PLEASE DO THAT,  
23 NOTWITHSTANDING MY OWN ENTHUSIASM FOR WHAT YOU'VE DONE.

24 MR. HARRISON: I'M SORRY I HAVE TO INTERRUPT  
25 JUST TO EXPRESS ONE WORD OF CAUTION. WE DO NEED TO BE

1 CAREFUL ABOUT COMMUNICATIONS BETWEEN BOARD MEMBERS AND  
2 THE PRESIDENT IN BETWEEN MEETINGS ON A SUBJECT THAT'S  
3 PENDING BEFORE THE BOARD. WE JUST NEED TO MAKE SURE  
4 THAT WE AVOID A SERIAL DISCUSSION AMONG A QUORUM OF  
5 MEMBERS.

6 DR. FRIEDMAN: ONLY INDIVIDUAL COMMUNICATIONS  
7 BETWEEN A PERSON AND THE PRESIDENT AND NO OTHER SERIAL  
8 COMMUNICATIONS.

9 MR. HARRISON: AS LONG AS WE DON'T HAVE 19  
10 MEMBERS CONTACTING THE PRESIDENT WITH THEIR OWN  
11 INDIVIDUAL POINTS OF VIEW, THAT'S FINE. BUT IF WE DO,  
12 THAT'S WHERE WE RUN INTO A PROBLEM, SO WE REALLY TRY TO  
13 DISCOURAGE.

14 CHAIRMAN KLEIN: DR. HALL CAN KEEP ME  
15 ADVISED, AND I'LL TRY AND MAKE CERTAIN THAT WE STAY  
16 WITHIN THE LIMITS WHILE HAVING THE QUALITY INTERFACE  
17 THAT I'M SURE DR. HALL AND THE BOARD MEMBERS --

18 DR. HALL: I ALWAYS WELCOME SUGGESTIONS FROM  
19 INDIVIDUAL BOARD MEMBERS ON ANY MATTER. SO PLEASE FEEL  
20 FREE.

21 DR. POMEROY: I WOULD JUST LIKE TO MAKE A  
22 STATEMENT FOR THE RECORD, WHICH IS THAT I AM  
23 EXTRAORDINARILY DISAPPOINTED THAT WE WILL NOT HAVE A  
24 QUORUM TO VOTE ON THIS TODAY BECAUSE I THINK ZACH MADE  
25 THE POINT WELL, THAT IF WE ARE GOING TO GET THIS DONE

1 IN TIME TO ACCOMPLISH OUR MISSION, WE SHOULD BE  
2 STARTING NOW. AND I WOULD JUST CALL ON MY FELLOW BOARD  
3 MEMBERS TO THINK ABOUT THE FACT THAT THIS WAS OUR  
4 RESPONSIBILITY, WE GAVE ZACH A CHARGE, AND I BELIEVE HE  
5 LIVED UP TO IT ADMIRABLY. AND I FEEL THAT WE HAVE NOT  
6 CARRIED THROUGH ON OUR RESPONSIBILITY THE WAY WE SHOULD  
7 HAVE IN ORDER TO GET THIS GOING IN A MORE TIMELY  
8 FASHION.

9 MS. LANSING: I AGREE.

10 DR. PIZZO: I'M ACTUALLY PLEASED TO SAY THAT  
11 I WAS GOING TO MAKE VIRTUALLY THE SAME COMMENT THAT YOU  
12 DID, CLAIRE. AND I THINK WHAT I'M WORRIED ABOUT, AND I  
13 THINK WE'VE HEARD GOOD REASONS FOR WORRY, IS THAT THE  
14 CLOCK IS TICKING, AND WE DON'T WANT TO BE LEFT WITHOUT  
15 THE INFORMATION. AND I THINK IT'S UNFORTUNATE THAT THE  
16 NEXT BOARD MEETING IS NOT TILL APRIL, SO WE LOSE TWO  
17 MONTHS IN THE PROCESS. I WONDER WHETHER THERE AREN'T  
18 THINGS THAT WE CAN DO DURING THAT TIME. CERTAINLY ONE  
19 THING THAT YOU ARTICULATED, ZACH, IS THAT THE  
20 INTERNATIONAL CANADIAN GROUP HAD COME FORWARD WITH  
21 SOMETHING THAT LOOKED INTERESTING. I HOPE THAT WE CAN  
22 PROCESS THAT.

23 DR. HALL: THAT DOES NOT REQUIRE APPROVAL BY  
24 THE ICOC BECAUSE IT'S INDEPENDENT OF THIS BECAUSE THAT  
25 WILL BE AN EXPENDITURE UNDER \$100,000.

1                   SO LET ME JUST SAY THAT I DO TAKE THE CHARGE  
2   OF THE BOARD SERIOUSLY. I APPRECIATE THE MANY  
3   SUGGESTIONS THAT YOU'VE MADE HERE AND THE COMMENTS, AND  
4   WE WILL GO FORWARD WITH THE PLANNING PROCESS BETWEEN  
5   NOW AND THE APRIL MEETING, AND WE WILL DEAL WITH THE  
6   ISSUE OF THE FINANCES AS BEST WE CAN.

7                   DR. PENHOET: IS IT POSSIBLE FOR US TO HAVE A  
8   PROPERLY NOTICED TELEPHONIC BOARD MEETING TO ADDRESS  
9   JUST THIS SUBJECT?

10                  MS. LANSING: THAT'S MY SAME QUESTION.

11                  MR. HARRISON: YES. AS LONG AS IT'S PROPERLY  
12   NOTICED, YOU CAN HAVE A TELECONFERENCE MEETING.

13                  MS. LANSING: I WOULD LIKE TO RECOMMEND THAT  
14   WE PROPERLY NOTICE IT, WE HAVE A TELEPHONIC CONFERENCE  
15   CALL AMONG ALL THE MEMBERS, MAKING SURE WE GET A QUORUM  
16   SO THAT THE DATES HAVE TO BE WORKED OUT, AND CALL FOR  
17   THE VOTE AT THAT TIME.

18                  DR. BRYANT: DO IT IN TEN DAYS.

19                  DR. HALL: THANK YOU.

20                  CHAIRMAN KLEIN: THANK YOU, DR. HALL. OUR  
21   VICE CHAIR NEEDS TO ALSO LEAVE. WE HAVE --

22                  DR. PIZZO: MOVE WE ADJOURN THE MEETING.  
23   THAT'S A JOKE.

24                  CHAIRMAN KLEIN: IF WE COULD JUST HAVE  
25   INTERIM INFORMATIONAL ITEMS FROM DR. HALL ON ITEM 16

1       AND 17 BASED UPON WHAT HE WOULD LIKE TO DO WITH THIS  
2       ITEM AT THIS TIME.

3                 DR. HALL:   LET ME SAY QUICKLY --

4                 MS. SAMUELSON:  I'D LIKE TO MAKE A REQUEST TO  
5       THE CHAIRMAN.  AS A MATTER OF PROCEDURE, I THINK IT  
6       WOULD BE WELL IF WHEN WE LOSE A QUORUM, WE STOP THE  
7       MEETING.  THERE ARE MANY OF US WE'VE DONE THIS BEFORE  
8       WHERE WE HANG AROUND AND TRY TO SQUEEZE IN OTHER  
9       THINGS.  WHATEVER IS COMMUNICATED ISN'T BEING DONE FOR  
10      THE BENEFIT OF THE FULL COMMITTEE.  AND I THINK IT  
11      MIGHT BE THAT THERE'S JUST SO MUCH AIR IN THAT BALLOON  
12      ON A GIVEN DAY.  WE START AT 8:30.  WE DIDN'T EVEN TAKE  
13      A BATHROOM BREAK UNTIL 1:18.  WE WORKED THROUGH LUNCH,  
14      A MEAGER LUNCH IT WAS, AND AT SOME POINT WE'VE DONE THE  
15      WORK PRODUCT WE CAN MANAGE IN A GIVEN DAY, AND WE'VE  
16      ACCOMPLISHED AN ENORMOUS AMOUNT TODAY.  RATHER THAN  
17      BEATING OURSELVES FOR WHAT WE HAVEN'T DONE, WHY DON'T  
18      WE SAY JOB WELL DONE AND GO HOME AND THEN START AGAIN  
19      ANOTHER TIME WITH THE SORT OF BREAKS AND SUSTENANCE  
20      THAT'S REQUIRED TO DO THIS VERY DIFFICULT WORK.

21                CHAIRMAN KLEIN:  JOAN, I WOULD SUGGEST THAT  
22      WHAT WE'RE TALKING ABOUT HERE ARE TWO ITEMS THAT ARE  
23      MAYBE FIVE MINUTES, AND WE COULD MAKE SURE THAT SINCE  
24      THEY'RE PURELY INFORMATIONAL AND WE'RE GOING TO COME  
25      BACK TO THE BOARD FOR THE NEXT MEETING, THAT WE FORWARD

1 TO THE BOARD THESE COMMENTS FROM THE TRANSCRIPT SO THAT  
2 PEOPLE ARE AWARE OF THEM COMING INTO THE MEETING, BUT  
3 IT'S VERY LIMITED COMMUNICATION IN THIS CASE.

4 MS. SAMUELSON: THEN WE CAN GET IT IN THE  
5 MAIL.

6 DR. HALL: I HAVE AN INFORMATIONAL ITEM  
7 THAT'S LESS THAN FIVE MINUTES. I SIMPLY WANT TO REPORT  
8 TO YOU THAT OUR DISCUSSIONS WITH THE PUBLIC LIBRARY OF  
9 SCIENCE HAVE NOT GONE AS FAST AS WE HAD HOPED. AND I  
10 HAD HOPED TO BRING TO THIS MEETING A PLAN FOR HOW WE  
11 WERE GOING TO DEVELOP THAT. WE HAVE NOT. HOWEVER, IN  
12 THE INTERIM, WE HAVE PICKED UP A VERY IMPORTANT  
13 PARTNER, AND THAT IS THE NEW YORK STEM CELL FOUNDATION  
14 HAS INDICATED THEIR DESIRE TO PARTICIPATE WITH US ON AN  
15 EQUAL BASIS IN CO-SPONSORING THIS VENTURE AND HAVE  
16 JOINED OUR DISCUSSIONS. AND I VIEW THAT AS A SORT OF  
17 WONDERFUL THING. THE TWO BOOKENDS OF THE COUNTRY HERE,  
18 NEW YORK AND CALIFORNIA, THAT MIGHT BE ABLE TO DO  
19 SOMETHING IN STEM CELL PUBLISHING.

20 CHAIRMAN KLEIN: DR. HALL, I BELIEVE THAT IT  
21 IS ALSO IMPORTANT THAT AT LEAST WE PUT INTO THE PUBLIC  
22 RECORD SO THAT WE CAN GET THE INFORMATION TO THE  
23 SCIENTIFIC INSTITUTIONS IN THE STATE WHAT OUR INTENTION  
24 IS ON OUR TIMETABLE FOR OUR GENERAL GRANT  
25 ADMINISTRATION PROCESS. BY PUTTING IT IN THE RECORD,

1 WE CAN THEN DISTRIBUTE THE INFORMATION TO INSTITUTIONS  
2 THROUGHOUT THE STATE, AND ONLY FOR THAT PURPOSE, JOAN.

3 DR. CHIU: TWO MINUTES. THANK YOU. JUST  
4 INFORMATIONAL ITEM. I WON'T EVEN SHOW ANY SLIDES.  
5 PLEASE TURN TO YOUR BINDERS TO TAB 17.

6 WE HAVE NOW COME UP -- WELL, YOU ARE FAMILIAR  
7 WITH AND AT THE LAST MEETING YOU APPROVED THE INTERIM  
8 GRANTS ADMINISTRATION POLICY FOR TRAINING GRANTS, WHAT  
9 WE CALL INTERNALLY AS THE BABY GAP. AND THANKS TO YOUR  
10 APPROVAL, WE CAN NOW MOVE FORWARD WHEN FUNDS BECOME  
11 AVAILABLE TO FUND TRAINING GRANTS.

12 WHAT WE PRESENT HERE TODAY FOR YOUR PERUSAL  
13 IS THE BIG GAP, WHICH IS THE GRANTS ADMINISTRATION  
14 POLICY, A DRAFT OF THE INTERIM ONE, FOR ALL AWARDS. SO  
15 PLEASE TAKE A GOOD LOOK AT IT DURING THE TWO MONTHS  
16 BEFORE OUR NEXT MEETING, AND WE WOULD LIKE YOUR  
17 COMMENTS AND HOPEFULLY YOUR APPROVAL NEXT TIME. THANK  
18 YOU.

19 CHAIRMAN KLEIN: THANK YOU. THE MEETING  
20 STANDS ADJOURNED EXCEPT IS THERE ANY CLOSING PUBLIC  
21 COMMENT? SEEING NO PUBLIC COMMENT, THE MEETING STANDS  
22 ADJOURNED. THANK YOU.

23 (THE MEETING WAS THEN ADJOURNED AT 04:46  
24 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND  
REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY  
CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE  
PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT  
COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE  
MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT  
THE LOCATION INDICATED BELOW

STANFORD UNIVERSITY  
326 GALVEZ STREET  
STANFORD, CALIFORNIA  
ON  
FRIDAY, FEBRUARY 10, 2006

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE  
ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS  
THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED  
STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO  
CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE  
RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152  
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